

Official Title: A Phase 2, Multicenter, Randomized, Double-blind, Placebo- and Active-controlled Trial of Brexpiprazole (1 - 3 mg/day) as Monotherapy or as Combination Therapy in the Treatment of Adults with Post-traumatic Stress Disorder

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Documentation of Statistical Methods

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Otsuka Pharmaceutical Development & Commercialization, Inc.

Investigational New Drug

Brexipiprazole (OPC-34712)

A Phase 2, Multicenter, Randomized, Double-blind, Placebo- and Active-controlled Trial of Brexipiprazole (1 - 3 mg/day) as Monotherapy or as Combination Therapy in the Treatment of Adults with Post-traumatic Stress Disorder

Protocol No. 331-201-00061

IND No. 117,549

Statistical Analysis Plan

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1 Introduction

This statistical analysis plan (SAP) documents the statistical methodology and data analysis algorithms and conventions to be applied for statistical analysis and reporting of efficacy and safety data of study 331-201-00061. All amendments to the protocol and Addendum to protocol amendment are taken into consideration in developing this SAP.

2 Study Objectives

Primary: To evaluate the efficacy of brexpiprazole as monotherapy or as combination treatment therapy with Zoloft (sertraline) in adult subjects with post-traumatic stress disorder (PTSD).

Secondary: To evaluate the safety and tolerability of brexpiprazole 1 to 3 mg/day as monotherapy or as combination treatment with Zoloft (sertraline) in adult subjects with PTSD.

3 Trial Details

3.1 Study Design

This is a phase 2, randomized, double-blind, placebo- and active-controlled, 4-arm trial to evaluate the efficacy, safety and tolerability of brexpiprazole (1 - 3 mg/day) as monotherapy or as combination therapy with Zoloft (sertraline) in adult subjects with PTSD. See [Figure 3.1-1](#) for a schematic of the trial design.

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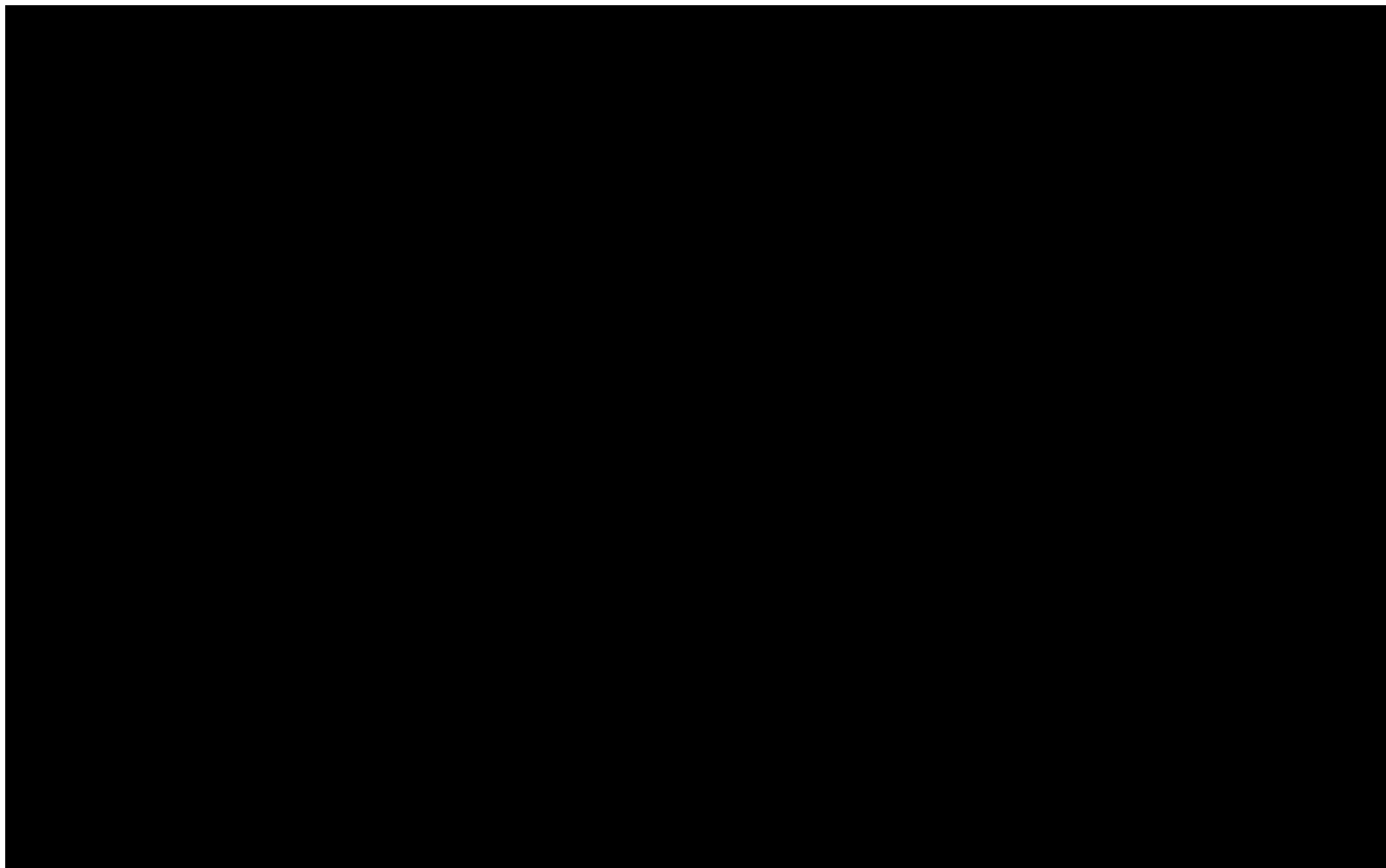


Figure 3.1-1 Unblinded Trial Design Schematic

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The trial will be organized as follows:

Screening Phase: The screening period will be 14 days and will begin when informed consent is signed. An extension can be requested from the medical monitor, if needed to meet eligibility requirements. The purpose of the screening period is to assess eligibility criteria at 1 or more visits (as necessary to complete screening assessments) and to washout prohibited concomitant pharmacotherapy, if applicable. An interactive response technology (IRT) or equivalent will be used to obtain an identification (ID) number for each subject with documented consent. Subjects will be between 18 and 65 years of age, inclusive, at the time of screening and will have a diagnosis of PTSD as defined by Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) criteria.

All subjects must agree to discontinue all prohibited medications during the screening period in order to meet the protocol-specified washout periods.

[REDACTED]

Blinded Phase B (Treatment Phase): At Week 1, subjects will be randomly assigned in a 1:1:1:1 ratio to one of one of the following double-blind treatment regimens:

- brexpiprazole monotherapy
- brexpiprazole and Zoloft (sertraline) combination therapy
- Zoloft (sertraline) monotherapy
- placebo

Subjects will attend visits at Baseline (Day 0) and Weeks 1, 2, 3, 4, 6, 8, 10, and 12 during the treatment phase.

Follow-up: If any subject discontinues the trial early, every effort should be made to complete the Week 12/early termination (ET) evaluations as soon as possible and whenever possible prior to starting any new medication or treatment. All subjects (completers and early withdrawals) will be contacted to monitor for safety events via telephone or clinic visit for 14 (+ 2) days after the last dose of investigational medicinal product (IMP). Any subject who withdraws because of a serious adverse event (SAE) should be seen in the clinic, if possible.

3.2 Trial Treatments

During [REDACTED] Phase B, all subjects receive daily: one tablet (active or placebo-matched brexpiprazole) and two Zoloft (sertraline) capsules (active or placebo-matched).

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3.2.1 Trial Treatment Administration

During Phase B (treatment phase), subjects will receive IMP, consisting of brexpiprazole monotherapy, brexpiprazole + Zoloft (sertraline), Zoloft (sertraline) monotherapy, or placebo, depending on the subject's treatment assignment.

All doses of IMP should be taken together at the same time each day, if possible. All doses of IMP can be taken without regard to meals. If tolerability issues arise, the timing of administration of the IMP may be adjusted at the investigator's discretion in order to achieve optimum tolerability and compliance.

3.2.2 Brexpiprazole Administration

[REDACTED]

[REDACTED] Dose decreases can occur at scheduled or unscheduled visits, but dose increases can occur only at scheduled visits. No dose decreases are allowed after the Week 6 visit and no dose increases are allowed after the Week 4 visit.

[REDACTED]

3.2.3 Combination of Brexpiprazole plus Zoloft (Sertraline)

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Dose decreases can occur at scheduled or unscheduled visits, but dose increases can occur only at scheduled visits. No dose decreases are allowed after the Week 6 visit and no dose increases are allowed after the Week 4 visit.

3.2.4 Zoloft (Sertraline) Administration

[REDACTED]

[REDACTED]

[REDACTED]

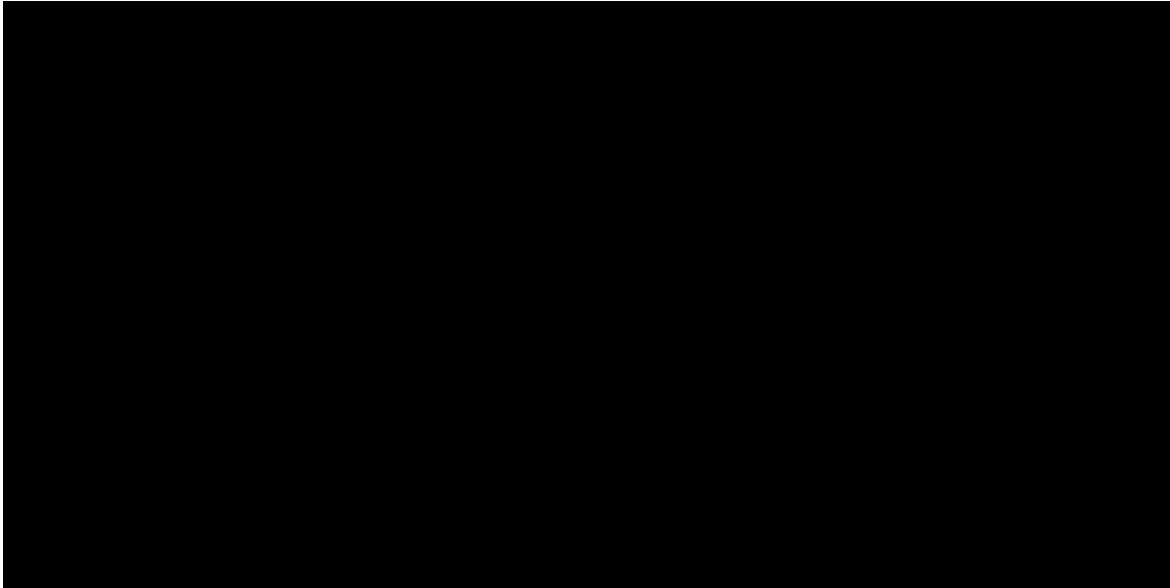
[REDACTED]

[REDACTED]

[REDACTED]

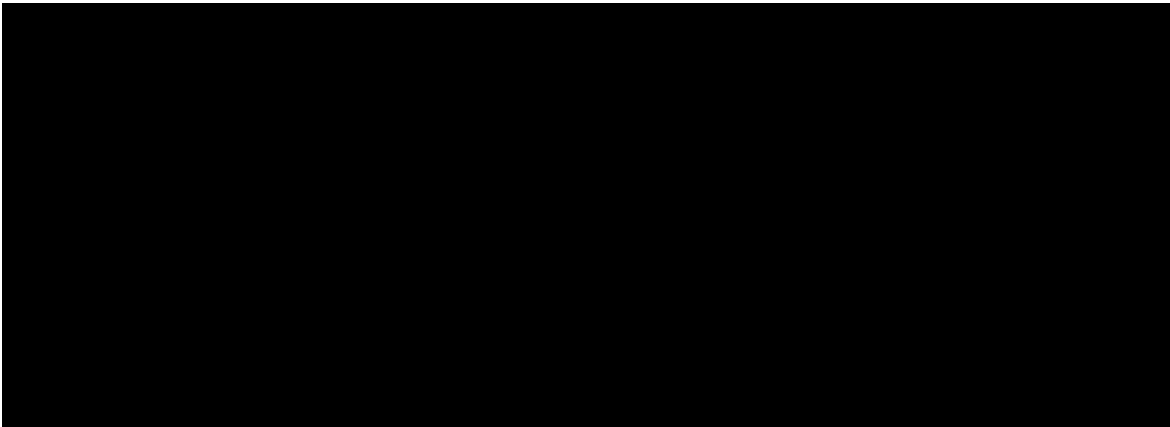
[REDACTED] Dose decreases can occur at scheduled or unscheduled visits, but dose increases can occur only at scheduled visits. No dose decreases are allowed after the Week 6 visit and no dose increases are allowed after the Week 4 visit.

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3.2.5 Placebo Administration

As shown in [Table 3.2.5-1](#), subjects assigned to placebo for both treatments (sertraline and brexpiprazole).



4 Sample Size and Power Justification

The primary efficacy endpoint is defined as change from baseline (Week 1 visit) [REDACTED] [REDACTED] in the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) total score.

Sixty-eight subjects per arm will provide at least 80% power at a 2-sided alpha level of 0.05 to detect the treatment difference of -6.5 points in primary efficacy endpoint for active arm vs placebo with a standard deviation (SD) of 13. Adjusting for 10% non-evaluable subjects, the total number of subjects to be randomized is 75 per treatment arm.

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Further adjusting for 10% dropout between Baseline (Day 0) Visit and randomization, approximately 332 subjects are expected to be enrolled in the trial.

5 Data Sets for Analysis and Missing Data

5.1 Data Sets for Analysis

The following analysis samples are defined for this trial:

Enrolled Sample: comprises all subjects enrolled [REDACTED]

Randomized Sample: comprises all subjects randomized into this trial

Safety Sample: comprises all subjects in the Randomized Sample who were administered at least one dose of double-blind IMP

Intent to Treat (ITT) Sample: comprises of all subjects in the Randomized Sample who took at least one dose of double-blind IMP and have a baseline and at least one post baseline evaluation for the CAPS-5 total score

To evaluate the efficacy of the study drug on the placebo non-responders, the following analysis sample is added.

The modified ITT Sample (mITT): comprises those subjects in the ITT Sample who meet the following two criteria:

- 1) CAPS-5 total score is at least 27 at the randomization visit (Week 1).
- 2) Improvement (in terms of reduction in CAPS-5 total score) in CAPS-5 total score is less than 30% at end of the placebo run-in phase (from Baseline (Day 0) to randomization visit (Week 1)).

In general, baseline of an efficacy endpoint is defined as the last available measurement before the first dose of double-blind IMP.

5.2 Handling of Missing Data

The CAPS-5 is a clinician-rated, structured interview designed to assess PTSD diagnostic status and symptoms severity as defined by the DSM-5. This trial will use the CAPS-5 Past Month and CAPS-5 Past Week versions of the scale. The CAPS-5 comprises questions that target the onset and duration of symptoms, subjective distress, impact of symptoms on social and occupational functioning, improvement in symptoms since a previous CAPS-5 administration, overall response validity, overall PTSD severity, and specifications for the dissociative subtype (depersonalization and derealization).

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The CAPS-5 total symptom severity score is calculated by summing severity scores for the 20 DSM-5 PTSD symptoms (items 1-20) from the following categories:

Category B: Intrusion symptoms (5 items);

Category C: Avoidance symptoms (2 items);

Category D: Cognition and mood symptoms (7 items); and

Category E: Arousal and reactivity symptoms (6 items)

If there are more than 1 item in each of categories B, D and E with a missing score, or any item in Category C with a missing score, the CAPS-5 total score is set to missing. For each category (B, D or E) with a missing score, the imputed subscores for that category is the average of the existing scores in the category multiplied by the total number of questions in the category. The CAPS-5 total score will then be imputed by adding all the subscores from categories B, C, D and E.

In general, missing data will be handled by analysis of mixed-effect model repeated measures (MMRM) methodology based on observed-case (OC) data from protocol-specified visits under the assumption of missing at random.

MMRM assumes data are missing at random (MAR), which is a reasonable assumption in longitudinal clinical trials in PTSD¹. However, the possibility of “missing not at random” (MNAR) data can never be ruled out. As sensitivity analyses, selection model², pattern-mixture model^{3,4,5,6}, and/or shared parameter model⁷ will be used to explore data missing mechanisms of MNAR and investigate the response profile of dropout reason. Details are provided in [Section 8.1.3 Sensitivity Analysis](#).

The Observed Cases (OC) data set will consist of actual observations recorded at each visit during Phase B and no missing data will be imputed. MMRM, Wu-Bailey, and pattern-mixture model will be performed on the OC dataset.

The Last Observation Carried Forward (LOCF) data set will include data recorded at a scheduled Phase B visit or, if no observation is recorded at that visit, data carried forward from the previous scheduled Phase B visit. Baseline (Week 1 visit) data will not be carried forward to impute missing values for the LOCF data set. The analysis of covariance (ANCOVA) analysis will be performed for the change from baseline [REDACTED] in blinded phase B (LOCF) in CAPS-5 total score as sensitivity analysis. The ANCOVA_LOCF model includes treatment and study center as main effects, and baseline value as a covariate.

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For categorical response/remission variables, OC analyses will be performed in addition to LOCF analyses. Study center will not be included in the models for OC analyses.

6 Study Conduct

6.1 Subject Disposition, Completion Rate and Reasons for Discontinuation

Subject disposition will be summarized for the Randomized Sample by treatment group, and by center.

Subject completion rate and reasons for discontinuation will be summarized for the Randomized Sample by treatment group. Subject completion rate for Phase B will also be summarized by treatment group and week for the Randomized Sample.

6.2 Treatment Compliance

Based on the Investigational medicinal product (IMP) panel of the CRF, compliance in taking IMP is calculated by dividing the number of tablets/capsules taken by the total number of tablets/capsules the patients were scheduled to take during the study period. Compliance is calculated on double-blind IMP for Phase B. For lost-to-follow up patients, last IMP end date record will be used as the treatment end date.

6.3 Protocol Deviation

Protocol deviations will be summarized by center and type of deviation for randomized subjects by treatment group. A listing of protocol deviations will be provided.

7 Baseline Characteristics

7.1 Baseline Definition

[REDACTED]

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7.2 Demographic Characteristics

Baseline demographic characteristics include age, sex, race, ethnicity, height, weight, waist circumference, and body mass index (BMI). For the Randomized Sample, demographic characteristics will be summarized by treatment group.

Mean, range and standard deviation will be used to describe continuous variables such as age. Frequency distributions will be tabulated for categorical variables such as race.

7.3 Medical and Psychiatric History and Treatment for PTSD

A summary of medical and psychiatric history will be presented for the Randomized Sample (by treatment group and overall). Summarized data will include the number of years since index traumatic event that led to development of PTSD and the number of years since onset of first symptoms leading to the diagnosis of PTSD based on data collected in CRF page “Medical - Psychiatric History and Concomitant Medications Review”. A summary of PTSD treatment based on the Emory Treatment Resistance Interview (E-TRIP) will also be presented for the Randomized Sample (by treatment group and overall). Psychiatric medication taken prior to the start of IMP will be listed.

7.4 Neuropsychiatric Diagnosis

A summary of the MINI International Neuropsychiatric Interview (M.I.N.I.) will be presented for the Randomized Sample (by treatment group and overall). Summarized will be the number and percentage of patients who meet each diagnosis criteria, and number and percentage of patients with each primary diagnosis.

A summary of the Life Events Checklist (LEC-5) extended version will also be presented for the Randomized Sample (by treatment group and overall). Summarized will be the number and percentage of patients with each response to each question in Part 1.

In addition, a summary of the Ohio State University Traumatic Brain Injury Identification (OSU TBI-ID) method will be presented for the Randomized Sample (by treatment group and overall). Summarized will be the number and percentage of patients’ answers (yes/no) to each question in Part 1 and the first question in Part 3.

7.5 Baseline PTSD Evaluation

For the Randomized Sample, baseline PTSD scale evaluation will be summarized by treatment group and overall. The mean, median, range and standard deviation will be used to

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summarize the assessments of: CAPS-5 total score, Symptoms of Trauma Scale (SOTS) total score, Clinical Global Impression – Severity (CGI-S) Score, PTSD Checklist for DSM-5 (PCL-5) total score, and Hospital Anxiety and Depression Scale (HADS) subscale scores (depression and anxiety).

8 Efficacy Analysis

All efficacy analyses will be performed on the Intent to Treat Sample, and patients will be included in the treatment group as randomized. All efficacy analyses will also be performed on the mITT Sample unless specified otherwise. The sensitivity analyses and analyses for sleep-related endpoints will not be performed on the mITT Sample.

For analysis of Phase B data, the baseline measurement, which is defined in [Section 7.1](#), is considered as “baseline” for Phase B. Statistical comparisons are based on 2-sided, .05 significance levels.

8.1 Primary Efficacy Endpoint

The primary efficacy endpoint is the change from baseline [REDACTED] in the CAPS-5 total score.

8.1.1 Primary Efficacy Analysis

The objective of the primary analysis is to evaluate the efficacy of brexpiprazole as monotherapy or as combination treatment with Zoloft (sertraline) in adult subjects with PTSD.

The estimand for the primary efficacy analysis is the difference in outcome improvement if all subjects tolerated and adhered to their treatment. This approach is Estimand #3 recommended by the 2010 National Academy of Sciences’ National Research Council report on prevention and treatment of missing data and ICH E9 (R1) “Addendum to Statistical Principles for Clinical Trials on Choosing Appropriate Estimands and Defining Sensitivity Analyses in Clinical Trials”.

This estimand focuses on the efficacy of brexpiprazole as monotherapy or as combination treatment with Zoloft (sertraline) in change from the baseline in CAPS-5 total score. The objective of this trial is consistent with the election of an efficacy rather than effectiveness estimand.

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The primary analysis will be performed on the Intent to Treat Sample. Change from baseline in CAPS-5 total score will be analyzed using a Mixed Model Repeated Measures (MMRM) analysis with an unstructured (UN) variance covariance structure. The model will include fixed class-effect terms for treatment, trial site, type of trauma (combat related Yes/No), visit week, and an interaction term of treatment by visit week and include the interaction term of baseline values of CAPS-5 total score by visit week as a covariate. All scheduled visits during double-blind treatment will be included in the model but primary comparison will be performed [REDACTED].

In case there is a convergence problem with MMRM model with the UN variance covariance matrix, the following structures other than unstructured will be used in order of 1) heterogeneous toeplitz (TOEPH), 2) heterogeneous autoregressive of order 1 (ARH1), and 3) heterogeneous compound symmetry (CSH) and the first (co)variance structure converging to the best fit will be used as the primary analysis. If a structured covariance has to be used, the empirical “sandwich” estimator of the standard error of the fixed effects parameters will be used in order to deal with possible model misspecification of the covariance matrix.

Small centers will be defined as centers that do not have at least one evaluable subject (evaluable with regard to the primary efficacy variable) in each treatment arm and each type of trauma (combat related Yes/No) in Phase B. All small centers will be pooled to form “pseudo centers” for the purpose of analysis according to the following algorithm. Small centers will be ordered from the largest to the smallest based on the number of evaluable subjects (i.e., subjects who have baseline and at least one post-baseline value for the primary endpoint in Phase B). The process will start by pooling the largest of the small centers with the smallest of the small centers until a non-small center is formed. This process will be repeated using the centers left out of the previous pass. In case of ties in center size among the largest centers, the center with the smallest center code will be selected. In case of ties in center size among the smallest centers, the center with the largest center code will be selected. If any centers are left out at the end of this process, they will be pooled with the smallest pseudo centers, or if no pseudo centers exist, they will be pooled with the smallest non-small center.

The following 5 comparisons [REDACTED] after randomization will be estimated as the difference between Least Squares means utilizing the computing software SAS procedure PROC MIXED.

- Brexpiprazole plus Sertraline vs Placebo
- Brexpiprazole plus Sertraline vs Sertraline

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- Brexpiprazole plus Sertraline vs Brexpiprazole
- Brexpiprazole vs Placebo
- Sertraline vs Placebo (as assay sensitivity analysis)

The hierarchical testing procedure that was planned in the protocol will not be performed due to the exploratory nature of the PoC (Proof of Concept) study.

8.1.2 Technical Computation Details for Primary Efficacy Analysis

The SAS code for the PROC MIXED procedure to carry out the above MMRM analysis with an unstructured variance covariance structure is illustrated as follows:

```
proc mixed;
  class treatment center visit subjid traumatype;
  model change=treatment traumatype center visit treatment*visit baseline*visit / s cl
  ddfm=kenwardroger;
  repeated visit /type=un subject=subjid r rcorr;
  lsmeans treament*visit / pdiff cl alpha=0.05 slice=visit;
run;
```

8.1.3 Sensitivity Analyses

8.1.3.1 Sensitivity Analyses for Missing at Random (MAR) Assumption

Traditionally the dropout mechanisms are divided into three types ([Little, 1995](#)): (1) Missing Completely at Random (MCAR), in which the probability of dropout doesn't depend on the observed data and the missing data; (2) Missing at Random (MAR), in which the probability of dropout depends on the observed data, and (3) Missing Not at Random (MNAR), where the probability of dropout depends on the missing data and possibly the observed data.

Most of MNAR methods ([Diggle P, Kenward MG, 1994](#)) have treated all observations with dropout as if they fall within the same dropout type. In practice, we would find that different dropout reasons may be related to the outcomes in different ways, for example, detailed dropout reasons for this study are: adverse events (AE), lack of efficacy (LOE), lost to follow-up, protocol deviation, sponsor discontinued study, subject met (protocol specified) withdrawal criteria, subject was withdrawn from participation by the investigator, and subject withdrew consent to participate. Dropout due to an AE and LOE may lead to MNAR dropout. Subject withdrew consent may also lead to MNAR dropout. However, it is debatable whether a dropout caused by subjects withdrew consent is MAR or MNAR. Except AE, LOE, and subject withdrew consent, all the other dropout reasons may be assumed as either MCAR or MAR dropout.

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As sensitivity analyses for missing at random (MAR) assumption, analyses for missing not at random (MNAR) will be carried out. Pattern Mixture Models (PMM) based on Multiple Imputation (MI) with mixed missing data mechanisms will be used to investigate the response profile of dropout patients by last dropout reason under MNAR mechanism for the following three scenarios:

- 1) Dropout reasons due to either AE or LOE as MNAR
- 2) Dropout reasons due to either AE or LOE or subject withdrew consent as MNAR
- 3) All dropouts as MNAR

Delta Adjustment Imputation Methods

This MNAR sensitivity analysis is to departure from MAR assumption by progressively increasing the delta until conclusion from the primary analysis is overturned. The delta is 0%, 10%, 20%, 30%, ..., 100% of the expected treatment difference of 6.5 points and/or the observed treatment difference between the active arm and Placebo from the primary analysis of MMRM model until conclusion of the primary analysis is overturned. When $\text{delta}=0$ it is MAR. When $\text{delta} > 0$ it is MNAR.

- 1) Using Monte Carlo Markov Chain (MCMC) methodology from PROC MI to impute the intermittent missing data to a monotone missing pattern;
- 2) Using a standard MAR-based multiple imputation approach from PROC MI to impute the monotone missingness data
- 3) For patients in the treated group and with a dropout reason of AE or LOE or subject withdrew consent, a delta will be added for all the values after the dropout time.
- 4) Using MMRM model in the primary analysis to analyzed the completed data using PROC MIXED on the multiple imputed data
- 5) Obtaining the overall results using PROC MIANALYZE.

Placebo Based Imputation Methods

Similar to “Standard” multiple imputations, except parameters for imputation model obtained from only the placebo (control) group. Missing data for both placebo and drug group are imputed based on the imputation model derived from placebo data. If drug improved outcomes prior to dropout, this benefit is carried into subsequent imputed values, but will diminish over time in accordance with the correlation structure.

In addition, model based MNAR methods such as the shared parameter model ([Wu and Baily, 1989](#)) and random coefficient pattern mixture model ([Hedeker D, Gibbons RD, 1997](#)) will be also performed.

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LOCF and OC Analyses

Change from baseline for the CAPS-5 total score will be evaluated using ANCOVA [REDACTED] treatment and, in LOCF analyses, study center and type of trauma as main effects. For the OC analyses, study center and type of trauma will not be included in the model.

8.1.3.2 Sensitivity Analyses for Violation of Normality Assumption

The primary endpoint MMRM analysis is a maximum likelihood method that relies on normality assumption. Residual analyses will be carried out to examine model assumption.

In the case of gross violations of the normality assumptions, nonparametric van Elteren test⁸ (van Elteren, 1960) will be performed to compare treatment effect [REDACTED] on both LOCF dataset and Multiple Imputation (MI) data. The van Elteren test is a generalized Cochran-Mantel-Haenszel (CMH) procedure useful for stratified continuous data in non-normal setting. It belongs to a general family of Mantel-Haenszel mean score tests. The test is performed via SAS procedure PROC FREQ, by including CMH2 and SCORES=MODRIDIT options in the TABLE statement. The stratification factor is trial center and type of trauma.

In addition, other methods that are robust to distributional assumption will also be performed to provide different views on the primary efficacy result, these include generalized estimating equations (GEE), weighted GEE (WGEE), and MI-robust regression⁹.

For MI-van Elteren test and MI-robust regression, imputation datasets will be generated with SAS MI procedure, each dataset will be analyzed, then an overall estimate is derived with SAS MIANALYZE procedure.

8.1.4 Subgroup Analyses

Subgroup analyses of change from baseline (Week 1 visit) in CAPS-5 total score to every study week in Phase B will be performed by the following factors:

- Sex (Based on the biological status at birth)
- Race (White and All Other Races)
- Age (Age<55, and Age ≥55)
- [REDACTED]

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- [REDACTED]
- [REDACTED]
- Type of trauma (combat related Yes/No)
 - Presence/Absence of psychosocial support at baseline
 - Previous pharmacological treatment intervention for PTSD (Yes/No)
 - Use of the wearable device (Yes/No). Subjects who have actigraphy data are considered as using the wearable device.
 - Years since the index traumatic event (<5 , $\geq 5 - <10$, and ≥ 10 years)
 - Age group (Age <30 , Age $\geq 30 - <40$, and Age ≥ 40)

All subgroup analyses will be conducted using the same MMRM analysis as for the primary efficacy analysis except that the fixed class effect term for trial center and type of trauma will not be included in the model.

Interaction effects of treatment-by-subgroup will be assessed [REDACTED] for the subgroups identified in the previous paragraph. MMRM analyses will be performed by adding addition of terms for subgroup-by-week and treatment-by-subgroup-by-week. These treatment-by-subgroup interaction analyses will be presented in statistical documentation.

8.2 Other Efficacy Endpoints

Other efficacy variables are as follows:

- 1) Change from baseline in CAPS-5 for every trial week visit in Phase B [REDACTED];
- 2) Change from baseline for every trial week visit in Phase B in PTSD behavior cluster sub scores of CAPS-5:
 - re-experiencing cluster sub score
 - avoidance cluster sub score
 - negative cognitions and mood cluster sub score
 - arousal cluster sub score
- 3) Change from baseline for every trial week visit in Phase B in CGI-S score;
- 4) Response at each visit in Phase B as defined by:
 - decrease from baseline $\geq 30\%$ in CAPS-5 total score
 - decrease from baseline by > 11 points in CAPS-5 total score

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- 5) Shift in CAPS-5 PTSD severity category (moderate, severe or extreme at baseline to asymptomatic, mild, moderate, severe or extreme at each visit). The following categories are based on CAPS-5 total score.
 - 0 – 19 = asymptomatic/few symptoms,
 - 20 – 39 = mild PTSD/subthreshold,
 - 40 – 59 = moderate PTSD/threshold,
 - 60 – 79 = severe PTSD symptomatology
 - ≥ 80 = extreme PTSD symptomatology
- 6) Change from baseline in SOTS total score for every trial week visit in Phase B;
- 7) Change from baseline in HADS subscale score (anxiety and depression) for every trial week visit in Phase B;
- 8) Change from baseline in PCL-5 total score for every trial week visit in Phase B;
- 9) Sleep related endpoints (see [Section 8.3](#) for details)

The continuous efficacy endpoints will be analyzed using MMRM model similar to that of pre-specified for change from baseline in CAPS-5 total score, correcting for the relevant values at randomization.

The response in variables will be evaluated by the Cochran-Mantel-Haenszel (CMH) General Association Test controlling, in LOCF analysis, for study center and type of trauma.

LOCF and OC analyses using ANCOVA will also be conducted for the continuous efficacy endpoints. The LOCF analysis model includes baseline value as covariate, and, treatment trial center and type of trauma as main effects. For the OC analyses, the model includes terms for baseline value as covariate, and treatment as main effect; trial center and type of trauma will not be included in the model.

Statistical significance for analysis of all other efficacy variables (1) through (4) and (6) through (9) will be evaluated at a nominal 0.05 level (two-sided).

As assay sensitivity analysis, a comparison of sertraline versus placebo will be performed for other efficacy endpoints.

8.3 Analyses for Sleep-related Endpoints

The sleep-related endpoints are derived from the data downloaded from the wearable device. Use of the wearable device is optional. The analyses for sleep-related endpoints will include only subjects who agree to the use of the wearable device.

The sleep-related endpoints are as follows:

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- Change from baseline in sleep parameters (Sleep Efficiency, Wake after Sleep Onset, Total Sleep Time, and Sleep Latency) for every week in Phase B;
- Proportion of subjects within the normal range of each sleep parameter for every week in Phase B. The normal range of each sleep parameter is defined as follows:
 - Sleep Efficiency: 85% or greater
 - Wake after Sleep Onset: less than 40 minutes
 - Total Sleep Time: greater than 370 minutes
 - Sleep Latency: 10-20 minutes
- Shift in status (within or out of the normal range at baseline to within or out of the normal range at each week) for each sleep parameter

Change from baseline in sleep parameters will be analyzed similarly to other continuous efficacy endpoints. Proportion of subjects within the normal range of each sleep parameter will be analyzed similarly to the response in other efficacy endpoints.

Subgroup analyses of change from baseline in CAPS-5 total score and CGI-S score to every study week in Phase B will be performed by the status (within or out of the normal range) of sleep parameters (Sleep Efficiency, Wake after Sleep Onset, Total Sleep Time, and Sleep Latency) at baseline. Summary statistics will be provided.

Additionally, subgroup analyses of change from baseline (Week 1 visit) in sleep parameters to every study week in Phase B will be performed based on the following baseline characteristics. Summary statistics will be provided.

- Type of trauma (combat related Yes/No)
- History of TBI (Question 1 Yes/No in Step 1 of the OSU TBI-ID)
- Use (current, former or never) of tobacco, alcohol and drug substance based on Tobacco-Alcohol-Substance Use Review form. The use of current, former or never is defined as follows.
 - If subjects used any types of tobacco/alcohol/drug currently then the use at baseline is current; if subjects did not use any types of tobacco/alcohol/drug currently and used any types formerly then the use at baseline is former; otherwise the use at baseline is never.

Relationships between sleep parameters and the following scales will be explored using Pearson correlation coefficient.

- CAPS-5 total score
- CGI-S score

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- HADS subscale score (anxiety and depression)
- E6 'Sleep disturbance severity' (score ranging from 0 to 4) from CAPS-5
- Item 2 'Repeated, disturbing dreams of the stressful experience' (score ranging from 0 to 4) from PCL-5
- Item 20 'Trouble falling or staying asleep' (score ranging from 0 to 4) from PCL-5
- Item 1 'Re-experiencing' (score ranging from 1 to 7) from SOTS

Relationships between sleep parameters and the following binary scales will be explored using Chi-square test for independence between sleep parameters (within or out of normal range) and the clinical scales (yes or no) if data allow.

- E6 'Sleep disturbance symptom' (Yes/No) from CAPS-5
- Suicidality from C-SSRS. Suicidality is defined as report of at least one occurrence of any type of suicidal ideation or at least one occurrence of any type of suicidal behavior during assessment period (count each person only once).

The mean daily values of sleep parameters per patient per week will be calculated as the mean of the available daily values in 7 days interval prior to the week. Baseline (Week 1) value is the mean of the available daily values from 7 days prior to Day 1 (relative to the first day of double-blind IMP in Phase B). Week 2 value is the mean of the available daily values from Day 1 to Day 7, Week 3 value is the mean of the available daily values from Day 8 to Day 14, ... etc.

8.4 Exploratory Analysis

Exploratory efficacy analyses will be presented in Statistical Documentation.

Treatment-by-center interaction will be assessed [REDACTED] by including the treatment-by-center-by-visit interaction in the model. Results for study centers will be displayed from largest center to smallest center.

Line Item score will be performed for CAPS-5, HADS and PCL-5 on change from baseline [REDACTED] and for SOTS on change from baseline to Week 12 using the MMRM model for CAPS-5, SOTS, HADS and PCL-5, where Cohen's D Effect Size is the difference between the two means divided by their standard deviation [as defined by Cohen's D and reviewed on pages 4-6 from the Sage book "Effect Size for ANOVA Designs" (Vol 129) by [Cortina and Nouri](#)]. For MMRM (using SAS PROC MIXED), LSMean difference of treatment effects for the between brexpiprazole + sertraline vs placebo, brexpiprazole vs placebo, and brexpiprazole + sertraline vs sertraline, separately, and the corresponding standard error of the difference (Stderr) will be obtained with an Estimate statement. Let n1 and n2 denote the

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respective sample sizes of the two groups to compare, Effect Size = $d = (\text{LSMean1} - \text{LSMean2}) / \text{Sigma}$, where $\text{Sigma} = \text{Stderr} / \text{SQRT}(1/n1 + 1/n2)$.

9 Safety Analysis

Standard safety variables to be analyzed include Adverse Events (AEs), clinical laboratory tests, vital signs, body weight, waist circumference, BMI, 12-lead electrocardiograms (ECGs), and physical examinations. In addition, data from the following safety scales will be evaluated: Abnormal Involuntary Movement Scale (AIMS), Simpson-Angus Scale (SAS), Barnes Akathisia Rating Scale (BARS) and Columbia-Suicide Severity Rating Scale (C-SSRS).

Analyses of Phase B safety data will be performed on the Safety Sample unless indicated otherwise. In general, baseline of a safety variable is defined as the last observation of the variable before taking the first dose of IMP, unless specified otherwise. Prospectively defined criteria will be used to identify potentially clinically relevant abnormal values for clinical laboratory tests, vital signs, ECGs, and body weight.

9.1 Adverse Events

All adverse events will be coded by System Organ Class (SOC) and Preferred Term (PT) according to the Medical Dictionary for Regulatory Activities (MedDRA). AEs that are sex-specific, e.g., ovarian cancer, will have their incidence rates evaluated for the specific sex.

Treatment-emergent AEs (TEAEs) in Phase B are defined as AEs with an onset date on or after the start of double-blind IMP (Week 1). In more detail, TEAEs are all adverse events which started after start of double blind IMP;

Adverse events occurring up to 30 days after the last day of IMP will be included in the summary tables.

The incidence of the following events in Phase B will be tabulated by treatment group and overall using the Safety Sample:

- a) TEAEs
- b) TEAEs by severity

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- c) TEAEs potentially causally related to the IMP as assessed by the investigator
- d) TEAEs with an outcome of death
- e) Serious TEAEs
- f) TEAEs leading to discontinuations of the IMP

The above summaries (b), (e) and (f) will also be prepared for TEAEs potentially causally related to the IMP.

In addition, incidence of TEAE during Phase B of at least 5% in any treatment group other than placebo group, and also greater than placebo by SOC and PT will be provided.

Incidence of TEAEs by SOC and PT will be summarized for sex, race and age subgroups.

EPS-related AEs will be grouped into five categories.

- 1) Dystonic Events, which include cervical spasm, dystonia, emprosthotonos, muscle contractions involuntary, muscle rigidity, muscle spasms, muscle spasticity, myotonia, nuchal rigidity, oculogyration, opisthotonos, pleurothotonus, risus sardonicus, torticollis, and trismus;
- 2) Parkinsonian Events, which include akinesia, asterixis, athetosis, bradykinesia, cogwheel rigidity, essential tremor, extrapyramidal disorder, freezing phenomenon, gait festinating, hypertonia, hypokinesia, hypokinesia neonatal, intention tremor, masked facies, parkinson's disease, parkinsonian crisis, parkinsonian gait, parkinsonian rest tremor, parkinsonism, tremor, and tremor neonatal;
- 3) Akathisia Events, which include akathisia, hyperkinesia, and psychomotor hyperactivity;
- 4) Dyskinetic Events, which include ballismus, buccoglossal syndrome, choreoathetosis, clumsiness, dyskinesia, dyskinesia neonatal, dyskinesia oesophageal, fumbling, nodding of head, on and off phenomenon, and tardive dyskinesia;
- 5) Residual Events, which include chorea, huntington's chorea, muscle twitching, and myoclonus.

Unless otherwise specified, in general, analysis of safety data will be performed on observed case and for last visit.

9.2 Clinical Laboratory Tests

Summary statistics for routine clinical laboratory measurements and prolactin concentrations will be provided. For Phase B laboratory tests, change from baseline will be summarized by

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treatment group. Potentially clinically relevant (PCR) results in laboratory tests will also be summarized.

9.2.1 Clinical Laboratory Tests in Phase B

Potentially clinically relevant laboratory measurement test results in Phase B will be identified for the Safety Sample and will be summarized by treatment group and listed. Criteria for identifying laboratory values of potential clinical relevance are provided in [Appendix 2](#).

9.2.2 Drug Induced Liver Injury (DILI)

Total bilirubin level should be checked for any subject with increased ALT or AST levels \geq three times the upper normal limits (ULN) or baseline.

■ Reporting all DILI as SAE to the FDA based on Hy's Law:

- ☐ AST or ALT $\geq 3 \times$ ULN or baseline and
- ☐ T_Bili $\geq 2 \times$ ULN or baseline

A separate incidence table will be provided for DILI cases, and the corresponding listing will be provided for the Safety Sample during Phase B.

9.2.3 Metabolic Change

In addition to mean change from baseline, incidence of treatment emergent significant changes in fasting lipids, fasting glucose, and metabolic syndrome will be summarized by treatment group using the following criteria.

Criteria for Treatment-Emergent Significant Change in Lipids and Glucose		
LAB PARAMETER	BASELINE ¹	ANYTIME POST BASELINE
LDL Direct, Fasting (MG/DL)	Borderline 100-<160 Normal/Borderline <160 Normal <100 Any Value	High ≥ 160 High ≥ 160 Borderline/High ≥ 100 Increased ≥ 30
HDL Cholesterol, Fasting (MG/DL)	Normal ≥ 40 Any Value	Low <40 Decreased ≥ 20
Triglycerides, Fasting (MG/DL)	Normal <150 Borderline 150-<200 Normal/Borderline <200 Normal <150	High 200-<500 High 200-<500 High 200-<500 Borderline/High/Very High ≥ 150

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Criteria for Treatment-Emergent Significant Change in Lipids and Glucose		
LAB PARAMETER	BASELINE ¹	ANYTIME POST BASELINE
	Any Value	Increased ≥ 50
Glucose Fasting, Serum (MG/DL)	Normal < 100	High ≥ 126
	Impaired $100 - < 126$	High ≥ 126
	Normal/Impaired < 126	High ≥ 126
	Any Value	Increased ≥ 10

¹ BASELINE IS CALCULATED FROM WEEK 1

Criteria for Treatment-Emergent Metabolic Syndrome	
DESCRIPTION	ANYTIME POST BASELINE ¹
Central Obesity	Waist Circumference ≥ 102 cm(MALE), ≥ 88 cm (FEMALE)
Dyslipidemia	Triglycerides ≥ 150 mg/dl
Dyslipidemia	HDL < 40 mg/dl (MALE), < 50 mg/dl (FEMALE)
Supine Blood Pressure	Systolic ≥ 130 mmHg and Diastolic ≥ 85 mmHg
Glucose Fasting, Serum	≥ 100 mg/dl
Metabolic Syndrome	Met 3 Or More of the Above Criteria at a Visit

¹ BASELINE IS CALCULATED FROM WEEK 1

9.3 Vital Signs

Summary statistics for vital signs will be provided. For Phase B vital signs, change from baseline (Week 1 visit) will be summarized for the Safety Sample by treatment group.

Potentially clinically relevant vital signs measurements identified in Phase B for the Safety Sample will be summarized by treatment group. Criteria for identifying vital signs of potential clinical relevance are provided in [Appendix 1](#). All potentially clinically relevant events or changes will be listed and included in summary tables.



9.4 12-Lead ECG

Summary statistics and incidence of potentially clinically relevant changes will be provided for ECG parameters.

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For the analysis of QT and QTc, data from three consecutive complexes (representing three consecutive heart beats) will be measured to determine average values. The following QT corrections will be used for reporting purposes in the clinical study report:

- 1) QTcB is the length of the QT interval corrected for heart rate by the Bazett formula:
 $QTcB = QT / (RR)^{0.5}$ and
- 2) QTcF is the length of the QT interval corrected for heart rate by the Fridericia formula:
 $QTcF = QT / (RR)^{0.33}$
- 3) QTcN is the length of the QT interval corrected for heart rate by the FDA Neuropharm Division formula: $QTcN = QT / (RR)^{0.37}$

Potentially clinically relevant changes in the 12-lead ECG identified in Phase B for the Safety Sample will be listed and summarized by treatment group. Criteria for identifying ECG measurements of potential clinical relevance are provided in [Appendix 3](#).

Categorical changes in ECG parameters during Phase B will be summarized based on the following criteria:

Categorical Change Criteria in QT/QTc Parameters		
Classification	Category	Criteria
QT	New Onset (> 450 Msec)	New onset (>450 msec) in QT means a subject who attains a value > 450 msec during treatment period but not at baseline.
QTc *	New Onset (\geq 450 Msec for men and \geq 470 Msec for women)	New onset (\geq 450 Msec for men and \geq 470 Msec for women) in QTc means a subject who attains a value \geq 450 Msec for men or \geq 470 Msec for women during treatment period but not at baseline.
	New Onset (\geq 450 Msec for men and \geq 470 Msec for women) And > 10% Increase	New onset (\geq 450 Msec for men and \geq 470 Msec for women) and > 10% increase in QTc means a subject who attains a value \geq 450 Msec for men or \geq 470 Msec for women, and > 10% increase during treatment period but not at baseline
	New Onset (> 500 Msec)	New onset (> 500 msec) in QTc means a subject who attains a value > 500 msec during treatment period but not at baseline.
	Increase 30 - 60 Msec	Increase from baseline value > 30 and \leq 60 msec in QTc
	Increase > 60 Msec	Increase from baseline value > 60 msec in QTc

* QTc categorical change criteria apply to QTcB, QTcF and QTcN.

9.5 Physical Examinations

By-patient listings will be provided for physical examination.

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9.5.1 Body Weight, Waist Circumference and BMI

Analyses of body weight, waist circumference and BMI will be performed for the Safety Sample. [REDACTED]

Body mass index is defined as weight in kilograms divided by the square of height in meters.

9.6 SAS, AIMS, and BARS

The mean change from baseline to every study week in Phase B obtained from the SAS total score, AIMS total score (total of the first 7 item scores), and the BARS Global Clinical Results will be presented for every scheduled visit, including Week 12.

Assessment will be tabulated and analyzed using ANCOVA. Analyses will be performed on the OC data set. In addition, analyses will be performed using the maximum (i.e. the worst) value observed during Phase B [REDACTED]

[REDACTED] The same analyses will be performed on the AIMS individual item scores 8, 9, and 10. In addition, incidence of BARS Global Clinical Assessment of Akathisia during Phase B by severity category will be provided. Analyses of these EPS rating scales will be performed for the Safety Sample.

9.7 Suicidality Data

Suicidality will be monitored during the study using the C-SSRS and will be summarized as number and percentage of subjects reporting any suicidal behavior, ideation, behavior by type (4 types), ideation by type (5 types) and treatment emergent suicidal behavior and ideation. Summary will be provided for Phase B. [REDACTED]

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Suicidality is defined as report of at least one occurrence of any type of suicidal ideation or at least one occurrence of any type of suicidal behavior during assessment period (count each person only once).

Treatment emergent suicidal behavior and ideation is summarized by four types: Emergence of suicidal ideation, Emergence of serious suicidal ideation, Worsening of suicidal ideation, Emergence of suicidal behavior.

Emergence of suicidal behavior/ideation is defined as report of any type of suicidal behavior/ideation during treatment when there was no baseline suicidal behavior/ideation.

Emergence of serious suicidal ideation is defined as observation of suicidal ideation severity rating of 4 or 5 during treatment when there was no baseline suicidal ideation.

Worsening of suicidal ideation is defined as a suicidal ideation severity rating that is more severe than it was at baseline.



9.8 Concomitant Medications

Number and proportion of patients taking concomitant medications prior to Phase B, during Phase B, and after study therapy are tabulated by drug classification using the WHO drug dictionary. For Phase B Randomized Sample, data will be presented by treatment group and overall.

9.9 Extent of Exposure

The start date of double-blind IMP will be the first day of double-blind dosing. The number and percentage of patients who receive double-blind IMP (brexpiprazole or sertraline), will be presented by week and by treatment group. Each dosing week will be based on the actual week; i.e., Day 1-7 in Week 1, Day 8-14 in Week 2, etc. This summary will be performed on the Safety Sample.

The mean daily dosage will be summarized by week and treatment group using descriptive statistics. The mean daily dosage per patient per week will be determined for each week of the study. This will be calculated by dividing the sum of individual total doses by the number of days in the week interval. The summary will contain for each treatment group the number of

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patients receiving double-blind IMP, and the mean and range of the mean daily dose for each week.

All the exposure analyses will be done for brexpiprazole or sertraline, separately.

10 Conventions

10.1 Study Visit Windows

Study visit windows will be used to map visits using study day intervals. This visit window convention applies to tables and listings for all efficacy and safety scales (CAPS-5, SOTS, CGI-S, PCL-5, HADS, SAS, AIMS, and BARS). This derived study window variable will be named as WEEK and will be footnoted. In listings it will be listed along with the CRF study visit.

Table 10.1A shows classifications for study day intervals in Phase B. The variable “target day” is defined using the number of days since the start of double-blind dosing in Phase B. The first day of double-blind dosing is defined as “Day 1”. [REDACTED]

If more than one observation falls within a particular study day interval, then the last observation within that interval is used. Evaluations occurring more than 7 days after the last double-blind dosing date will not be mapped into study visit windows, and will be excluded from the analysis.

Table 10.1A: Study Day and Visit Windows in Phase B

Week	Target Day ^a	Study Day Interval ^a
2	7	2-10
3	14	11-17
4	21	18-24
6	35	25-38
8	49	39-52
10	63	53-66
12	77	67-84 ^b

^a Relative to the first day of double-blind IMP in Phase B.

^b Evaluations occurring more than seven days after the last double-blind dosing date will be excluded from the Phase B analyses.

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10.2 Pooling of small centers

Primary efficacy analysis will be performed on the Intent to Treat Sample which comprises those subjects in the Randomized Sample who have a baseline value and at least one post-baseline value for CAPS-5 total score in Phase B. Small centers will be defined as centers that do not have at least one evaluable subject (evaluable with regard to the primary efficacy variable) in each treatment arm and each type of trauma (combat related Yes/No) in Phase B. All small centers will be pooled to form “pseudo centers” for the purpose of analysis according to the following algorithm. Small centers will be ordered from the largest to the smallest based on the number of evaluable subjects [REDACTED]

[REDACTED] at least one post-randomization value for CAPS-5 total score in Phase B). The process will start by pooling the largest of the small centers with the smallest of the small centers until a non-small center is formed. This process will be repeated using the centers left out of the previous pass. In case of ties in center size among the largest centers, the center with the smallest center code will be selected. In case of ties in center size among the smallest centers, the center with the largest center code will be selected. If any centers are left out at the end of this process, they will be pooled with the smallest pseudo centers, or if no pseudo centers exist, they will be pooled with the smallest non-small center.

Primary efficacy analysis will also be performed on the mITT Sample. The process of pooling of small centers for the analysis based on the mITT Sample is similar to the process for ITT Sample.

10.3 Scales: Rules for Scoring and Handling of Missing Data

10.3.1 CAPS-5

The CAPS-5 is a clinician-rated, structured interview designed to assess PTSD diagnostic status and symptoms severity as defined by the DSM-5. This trial will use the CAPS-5 Past Month and CAPS-5 Past Week versions of the scale. The CAPS-5 comprises questions that target the onset and duration of symptoms, subjective distress, impact of symptoms on social and occupational functioning, improvement in symptoms since a previous CAPS-5 administration, overall response validity, overall PTSD severity, and specifications for the dissociative subtype (depersonalization and derealization).

The CAPS-5 total symptom severity score is calculated by summing severity scores for the 20 DSM-5 PTSD symptoms (items 1-20) from the following categories:

Category B: Intrusion symptoms (5 items);

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Category C: Avoidance symptoms (2 items);

Category D: Cognition and mood symptoms (7 items); and

Category E: Arousal and reactivity symptoms (6 items)

If there are more than 1 item in each of categories B, D and E with a missing score, or any item in Category C with a missing score, the CAPS-5 total score is set to missing. For each category (B, D or E) with a missing score, the imputed subscores for that category is the average of the existing scores in the category multiplied by the total number of questions in the category. The CAPS-5 total score will then be imputed by adding all the subscores from categories B, C, D and E.

10.3.2 SOTS

The SOTS is a 12-item 7-point symptom severity rating scale designed to measure change. Ratings for each of the 12 symptoms can range from 1 = Absent to 7 = Extreme. Because the SOTS provides a means of rating of symptoms at 7 levels of severity (absent, minimal, mild, moderate, moderate severe, severe, and extreme), it can assess changes in trauma symptoms, which will become increasingly important as new interventions, both psychosocial and pharmacological, emerge.

The SOTS total score is calculated by summing scores from all 12 items. The SOTS total score will be un-evaluable if fewer than 10 of the 12 items are recorded. If 10 or 11 of the 12 items are recorded, the SOTS score will be the mean of the recorded items multiplied by 12 and then rounded to the first decimal place.

10.3.3 CGI-S

The severity of illness for each subject will be rated using the CGI-S. CGI-S items are: 0 = not assessed, 1 = normal, not at all ill, 2 = borderline mentally ill, 3 = mildly ill, 4 = moderately ill, 5 = markedly ill, 6 = severely ill, 7 = among the most extremely ill patients. The score 0 (= not assessed) will be set to missing. The CGI-S is therefore a 7-point scale from 1 through 7.

10.3.4 PCL-5

The PCL-5 is a checklist of problems that people sometimes have in response to a very stressful experience. Subjects need to indicate a number to the right of each problem to indicate how much they have been bothered by that problem in the past month. The scale rates items from 0 (not at all), 1 (a little bit), 2 (moderately), 3 (quite a bit), and 4 (extremely).

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The PCL-5 total score is calculated by summing severity scores for scores from all 20 items. The PCL-5 total score will be un-evaluable if fewer than 16 of the 20 items are recorded. If 16 to 19 of the 20 items are recorded, the PCL-5 total score will be the mean of the recorded items multiplied by 20 and then rounded to the first decimal place.

10.3.5 HADS

The HADS is a subject-rated scale designed to screen for anxiety and depressive states in medical subjects. The HADS consists of 2 subscales: The D-scale measures depression and the A-scale measures anxiety. Each subscale contains 7 items, and each item is rated from 0 (absent) to 3 (maximum severity). The score of each subscale is the sum of scores from each item in the subscale. Each subscale ranges from 0 to 21. The subscales will be analyzed separately. If there are more than 1 item with missing score for a give subscale, the score of the subscale is set to be missing. If 6 of the 7 items are recorded, the score of the subscale will be the mean of the recorded items multiplied by 7 and then rounded to the first decimal place.

10.3.6 SAS

The SAS will be used to evaluate extrapyramidal symptoms (EPS). It consists of a list of 10 symptoms of Parkinsonism (gait, arm dropping, shoulder shaking, elbow rigidity, wrist rigidity, head rotation, glabella tap, tremor, salivation, and akathisia). Each item will be rated on a 5-point scale, with a score of zero representing absence of symptoms, and a score of 4 representing a severe condition. The SAS Total score is the sum of ratings for all 10 items, with possible Total scores from 0 to 40. The SAS Total score will be un-evaluable if less than 8 of the 10 items are recorded. If 8 or 9 of the 10 items are recorded, the Total score will be the mean of the recorded items multiplied by 10 and then rounded to the first decimal place.

10.3.7 AIMS

The AIMS is a 12-item scale. The first 10 items are rated from 0 to 4 (0=best, 4=worst). An item score of 0, depending on the item, either means: no abnormal involuntary movement (AIM), or no incapacitation due to AIM, or no awareness of AIM. An item score of 4 either means: severe AIM, or severe incapacitation due to AIM, or being aware of, and severe distress caused by AIM. Items 11 and 12, related to dental status, have dichotomous responses, 0=no and 1=yes. The AIMS Total Score is the sum of the ratings for the first seven items. The possible total scores are from 0 to 28. The AIMS Total Score will be un-evaluable if less than 6 of the first 7 items are recorded. If 6 of the items are recorded, then the total

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score will be the mean of the recorded items multiplied by 7 and then rounded to the first decimal place.

10.3.8 BARS

The BARS consists of 4 items related to akathisia: objective observation of akathisia by the investigator, subjective feelings of restlessness by the subject, subjective distress due to akathisia, and global clinical assessment of akathisia. The first 3 items will be rated on a 4-point scale, with a score of zero representing absence of symptoms and a score of 3 representing a severe condition. The global clinical evaluation will be made on a 6-point scale, with zero representing absence of symptoms and a score of 5 representing severe akathisia.

10.3.9 C-SSRS

Suicidality will be monitored during the trial using the C-SSRS. This trial will use the “baseline/screening” and “Since Last Visit” versions of the scale. The “baseline/screening” version, which assesses the lifetime experience of the subject with suicide events and suicidal ideation and the occurrence of suicide events and/or ideation within a specified time period prior to entry into the trial, will be completed for all subjects at screening to determine eligibility. Any subject with active suicidal ideation within the last 6 months, suicidal behaviors within the last 2 years, or who in the clinical judgment of the investigator presents a serious risk of suicide should be excluded from the trial. The “Since Last Visit” C-SSRS form will also be completed at all visits after screening.

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11 References

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12 Potential Clinical Relevance Criteria from Protocol

Appendix 1 Criteria for Identifying Vital Signs of Potential Clinical Relevance

Variable	Criterion Value ^a	Change Relative to Baseline ^a
Heart Rate ^b	> 120 bpm < 50 bpm	≥ 15 bpm increase ≥ 15 bpm decrease
Systolic Blood Pressure ^b	> 180 mmHg < 90 mmHg	≥ 20 mmHg increase ≥ 20 mmHg decrease
Diastolic Blood Pressure ^b	> 105 mmHg < 50 mmHg	≥ 15 mmHg increase ≥ 15 mmHg decrease
Orthostatic Hypotension	≥ 20 mmHg decrease in systolic blood pressure and a ≥ 25 bpm increase in heart rate from supine to sitting/standing	Not Applicable (baseline status not considered)
Weight	-	≥ 7% increase ≥ 7% decrease

^a In order to be identified as potentially clinically relevant, an on-treatment value must meet the “Criterion Value” and also represent a change from the subject’s baseline value of at least the magnitude shown in the “Change Relative to Baseline” column.

^b As defined in “Supplementary Suggestions for Preparing an Integrated Summary of Safety Information in an Original NDA Submission and for Organizing Information in Periodic Safety Updates,” FDA Division of Neuropharmacological Drug Products draft (2/27/87).

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Appendix 2 Criteria for Identifying Laboratory Values of Potential Clinical Relevance

Laboratory Tests	Criteria
Chemistry	
AST (SGOT)	≥ 3 x upper limit of normal (ULN)
ALT (SGPT)	≥ 3 x ULN
Alkaline phosphatase	≥ 3 x ULN
Lactate dehydrogenase (LDH)	≥ 3 x ULN
Blood urea nitrogen (BUN)	≥ 30 mg/dL
Creatinine	≥ 2.0 mg/dL
Uric Acid	
Men	≥ 10.5 mg/dL
Women	≥ 8.5 mg/dL
Bilirubin (total)	≥ 2.0 mg/dL
Creatine phosphokinase (CPK)	≥ 3 x ULN
Prolactin	> ULN
Hematology	
Hematocrit	
Men	≤ 37 % and decrease of ≥ 3 percentage points from Baseline
Women	≤ 32 % and decrease of ≥ 3 percentage points from Baseline
Hemoglobin	
Men	≤ 11.5 g/dL
Women	≤ 9.5 g/dL
White blood count	≤ 2,800/ mm ³ or ≥ 16,000/ mm ³
Eosinophils	≥ 10%
Neutrophils	≤ 15%
Absolute neutrophil count	≤ 1,000/ mm ³
Platelet count	≤ 75,000/ mm ³ or ≥ 700,000/ mm ³
Urinalysis	
Protein	Increase of ≥ 2 units
Glucose	Increase of ≥ 2 units
Casts	Increase of ≥ 2 units
Additional Criteria	
Chloride	≤ 90 mEq/L or ≥ 118 mEq/L
Potassium	≤ 2.5 mEq/L or ≥ 6.5 mEq/L
Sodium	≤ 126 mEq/L or ≥ 156 mEq/L
Calcium	≤ 8.2 mg/dL or ≥ 12 mg/dL
Glucose	
Fasting	≥ 100 mg/dL
Non-Fasting	≥ 200 mg/dL
Total Cholesterol, Fasting	≥ 240 mg/dL
LDL Cholesterol, Fasting	≥ 160 mg/dL
HDL Cholesterol, Fasting	
Men	< 40 mg/dL
Women	< 50 mg/dL
Triglycerides, Fasting	≥ 150 mg/dL

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Appendix 3 Criteria for Identifying ECG Measurements of Potential Clinical Relevance

Variable	Criterion Value ^a	Change Relative to Baseline ^a
Rate		
Tachycardia	≥ 120 bpm	increase of ≥ 15 bpm
Bradycardia	≤ 50 bpm	decrease of ≥ 15 bpm
Rhythm		
Sinus tachycardia ^b	≥ 120 bpm	increase of ≥ 15 bpm
Sinus bradycardia ^c	≤ 50 bpm	decrease of ≥ 15 bpm
Supraventricular premature beat	all	not present \rightarrow present
Ventricular premature beat	all	not present \rightarrow present
Supraventricular tachycardia	all	not present \rightarrow present
Ventricular tachycardia	all	not present \rightarrow present
Atrial fibrillation	all	not present \rightarrow present
Atrial flutter	all	not present \rightarrow present
Conduction		
1° atrioventricular block	PR ≥ 200 msec	increase of ≥ 50 msec
2° atrioventricular block	all	not present \rightarrow present
3° atrioventricular block	all	not present \rightarrow present
Left bundle-branch block	all	not present \rightarrow present
Right bundle-branch block	all	not present \rightarrow present
Pre-excitation syndrome	all	not present \rightarrow present
Other intraventricular conduction block ^d	QRS ≥ 120 msec	increase of ≥ 20 msec
Infarction		
Acute or subacute	all	not present \rightarrow present
Old	all	not present \rightarrow present ≥ 12 weeks post study entry
ST/T Morphological		
Myocardial Ischemia	all	not present \rightarrow present
Symmetrical T-wave inversion	all	not present \rightarrow present
Increase in QTc	QTcF ≥ 450 msec (men) QTcF ≥ 470 msec (women)	

^a In order to be identified as potentially clinically relevant, an on-treatment value must meet the “Criterion Value” and also represent a change from the subject’s baseline value of at least the magnitude shown in the “Change Relative to Baseline” column.

^b No current diagnosis of supraventricular tachycardia, ventricular tachycardia, atrial fibrillation, atrial flutter, or other rhythm abnormality.

^c No current diagnosis of atrial fibrillation, atrial flutter, or other rhythm abnormality.

^d No current diagnosis of left bundle branch block or right bundle branch block.

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13 Proposed List of Summary Tables

- CT-1.1 Subject Disposition (Randomized Sample)
- CT-1.2 Subject Disposition by Center (Randomized Sample)
- CT-1.3 Subject Completion Rates by Week During Phase B (Randomized Sample)
- CT-1.4.1 Enrollment by Country (Randomized Sample)
- CT-1.4.2 Enrollment by Country by Age Group (Randomized Sample)

- CT-2.1 Reasons for Discontinuation in Phase B (Randomized Sample)

- CT-3.1.1 Demographic and Baseline Characteristics (Randomized Sample)
- CT-3.1.2 Demographic and Baseline Characteristics by Trauma Type (Randomized Sample)
- CT-3.1.3 Demographic and Baseline Characteristics by Use of Wearable Device (Randomized Sample)
- CT-3.1.4 Demographic and Baseline Characteristics by Placebo 20% Non-Responder Status (Randomized Sample)
- CT-3.1.5 Demographic and Baseline Characteristics by Placebo 25% Non-Responder Status (Randomized Sample)
- CT-3.1.6 Demographic and Baseline Characteristics by Placebo 30% Non-Responder Status (Randomized Sample)
- CT-3.2.1 Medical History (Randomized Sample)
- CT-3.2.2 Psychiatric History (Randomized Sample)
- CT-3.2.3 PTSD Treatment History Based on Emory Treatment Resistance Interview (E-TRIP) (Randomized Sample)
- CT-3.2.4 PTSD Disease History (Randomized Sample)
- CT-3.3.1 MINI International Neuropsychiatric Interview (M.I.N.I.) (Randomized Sample)
- CT-3.3.2 Summary on Life Events Checklist for DSM-5 (LEC-5) (Randomized Sample)
- CT-3.3.3 Summary on Ohio State University Traumatic Brain Injury Identification (OSU TBI-ID) Method (Randomized Sample)
- CT-3.4 Baseline Psychiatric Scale Evaluations (Randomized Sample)

- CT-4.1 Concomitant Medications: Medications Taken Prior to Start of Study Therapy (Safety Sample)
- CT-4.2 Concomitant Medications: Medications Taken During Phase B (Safety Sample)
- CT-4.3 Concomitant Medications: Medications Taken Post Study Therapy (Safety Sample)

- CT-5.1 Summary of Efficacy Results [REDACTED] (Intent to Treat Sample)
- CT-5.2.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - MMRM, UN (Intent to Treat Sample)
- CT-5.2.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - MMRM, TOEPH Empirical (Intent to Treat Sample)
- CT-5.2.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - MMRM, ARH1 Empirical (Intent to Treat Sample)

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- CT-5.2.4 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - MMRM, CSH Empirical (Intent to Treat Sample)
- CT-5.2.5 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - MMRM, DDFM=SATTERTHWAITE (Intent to Treat Sample)
- CT-5.2.6.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - LOCF (Intent to Treat Sample)
- CT-5.2.6.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - OC (Intent to Treat Sample)
- CT-5.2.7 Summary of Mean Change from Baseline (Day 0) [REDACTED] by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - OC (Intent to Treat Sample)
- CT-5.3.1 Summary of Mean Change [REDACTED] to Phase B in CAPS-5 Cluster Subscore - MMRM, UN (Intent to Treat Sample)
- CT-5.3.2 Summary of Mean Change [REDACTED] to Phase B in CAPS-5 Cluster Subscore - LOCF (Intent to Treat Sample)
- CT-5.3.3 Summary of Mean Change [REDACTED] to Phase B in CAPS-5 Cluster Subscore - OC (Intent to Treat Sample)
- CT-5.3.4 Summary of Mean Change from Baseline (Day 0) [REDACTED] in CAPS-5 Cluster Subscore - OC (Intent to Treat Sample)
- CT-5.4.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinical Global Impression Severity of Illness (CGI-S) Scale - MMRM, UN (Intent to Treat Sample)
- CT-5.4.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinical Global Impression Severity of Illness (CGI-S) Scale - LOCF (Intent to Treat Sample)
- CT-5.4.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinical Global Impression Severity of Illness (CGI-S) Scale - OC (Intent to Treat Sample)
- CT-5.4.4 Summary of Mean Change from Baseline (Day 0) [REDACTED] by Study Week in Clinical Global Impression Severity of Illness (CGI-S) Scale - OC (Intent to Treat Sample)
- CT-5.5.1 Summary of Proportion of Subjects with a Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Response During Phase B Relative [REDACTED] - LOCF (Intent to Treat Sample)
- CT-5.5.2 Summary of Proportion of Subjects with a Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Response During Phase B Relative [REDACTED] - OC (Intent to Treat Sample)
- CT-5.6.1 Summary of Proportion of Subjects with Shift in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Severity Category During Phase B Relative [REDACTED] - LOCF (Intent to Treat Sample)
- CT-5.6.2 Summary of Proportion of Subjects with Shift in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Severity Category During Phase B Relative [REDACTED] - OC (Intent to Treat Sample)
- CT-5.7.1 Summary of Mean Change from Baseline (Day 0) to Phase B by Study Week in Symptoms of Trauma Scale (SOTS) Total Score - MMRM, UN (Intent to Treat Sample)
- CT-5.7.2 Summary of Mean Change from Baseline (Day 0) to Phase B by Study Week in Symptoms of Trauma Scale (SOTS) Total Score - LOCF (Intent to Treat Sample)
- CT-5.7.3 Summary of Mean Change from Baseline (Day 0) to Phase B by Study Week in Symptoms of Trauma Scale (SOTS) Total Score - OC (Intent to Treat Sample)

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- CT-5.8.1 Summary of Mean Change from [REDACTED] to Phase B by Study Week in PTSD Checklist for DSM-5 (PCL-5) Total Score - MMRM, UN (Intent to Treat Sample)
- CT-5.8.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in PTSD Checklist for DSM-5 (PCL-5) Total Score - LOCF (Intent to Treat Sample)
- CT-5.8.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in PTSD Checklist for DSM-5 (PCL-5) Total Score - OC (Intent to Treat Sample)
- CT-5.8.4 Summary of Mean Change from Baseline (Day 0) [REDACTED] by Study Week in PTSD Checklist for DSM-5 (PCL-5) Total Score - OC (Intent to Treat Sample)
- CT-5.9.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Hospital Anxiety and Depression Scale (HADS) Subscale Score - MMRM, UN (Intent to Treat Sample)
- CT-5.9.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Hospital Anxiety and Depression Scale (HADS) Subscale Score - LOCF (Intent to Treat Sample)
- CT-5.9.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in Hospital Anxiety and Depression Scale (HADS) Subscale Score - OC (Intent to Treat Sample)
- CT-5.9.4 Summary of Mean Change from Baseline (Day 0) [REDACTED] by Study Week in Hospital Anxiety and Depression Scale (HADS) Subscale Score - OC (Intent to Treat Sample)
- CT-5.10.1.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Sleep Parameters – MMRM (Intent to Treat Sample)
- CT-5.10.1.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Sleep Parameters – LOCF (Intent to Treat Sample)
- CT-5.10.1.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in Sleep Parameters – OC (Intent to Treat Sample)
- CT-5.10.2.1 Summary of Proportion of Subjects Within Normal Range in Sleep Parameters During Phase B by Study Week – LOCF (Intent to Treat Sample)
- CT-5.10.2.2 Summary of Proportion of Subjects Within Normal Range in Sleep Parameters During Phase B by Study Week – OC (Intent to Treat Sample)
- CT-5.10.3 Summary of Proportion of Subjects with Shift in Sleep Parameters Relative [REDACTED] – OC (Intent to Treat Sample)
- CT-5.10.4.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score by Status of Sleep Parameters at Baseline – OC (Intent to Treat Sample)
- CT-5.10.4.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinical Global Impression Severity of Illness (CGI-S) Scale by Status of Sleep Parameters at Baseline – OC (Intent to Treat Sample)
- CT-5.10.5.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Sleep Parameters by Trauma Type – OC (Intent to Treat Sample)
- CT-5.10.5.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Sleep Parameters by History of TBI – OC (Intent to Treat Sample)
- CT-5.10.5.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in Sleep Parameters by Use of Alcohol – OC (Intent to Treat Sample)
- CT-5.10.5.4 Summary of Mean Change [REDACTED] to Phase B by Study Week in Sleep Parameters by Use of Drug Substance – OC (Intent to Treat Sample)

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CT-5.10.5.5 Summary of Mean Change [REDACTED] to Phase B by Study Week in Sleep Parameters by Use of Tobacco – OC (Intent to Treat Sample)

CT-5.10.6 Correlations between Sleep Parameters and Clinical Scales

CT-5.10.7 Relationship between Sleep Parameters and Categorical Clinical Scales

CT-5.11.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score – MI, VAN ELTEREN TEST (Intent to Treat Sample)

CT-5.11.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - GEE (Intent to Treat Sample)

CT-5.11.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - WGEE (Intent to Treat Sample)

CT-5.12.1 Sensitivity Analysis of MNAR using Pattern Mixture Model with Multiple Imputation (Delta Method 1) in CAPS-5 Total Score Assume All Dropouts as MNAR (Intent to Treat Sample)

CT-5.12.2 Sensitivity Analysis of MNAR using Pattern Mixture Model with Multiple Imputation (Delta Method 2) in CAPS-5 Total Score Assume All Dropouts as MNAR (Intent to Treat Sample)

CT-5.12.3 Sensitivity Analysis of MNAR using Pattern Mixture Model with Multiple Imputation (Delta Method 1) in CAPS-5 Total Score Dropout due to AE or LOE or Withdrew Consent as MNAR (Intent to Treat Sample)

CT-5.12.4 Sensitivity Analysis of MNAR using Pattern Mixture Model with Multiple Imputation (Delta Method 2) in CAPS-5 Total Score Dropout due to AE or LOE or Withdrew Consent as MNAR (Intent to Treat Sample)

CT-5.12.5 Sensitivity Analysis of MNAR using Pattern Mixture Model with Multiple Imputation (Delta Method 1) in CAPS-5 Total Score Dropouts due to AE or Lack of Efficacy (LOE) as MNAR (Intent to Treat Sample)

CT-5.12.6 Sensitivity Analysis of MNAR using Pattern Mixture Model with Multiple Imputation (Delta Method 2) in CAPS-5 Total Score Dropouts due to AE or Lack of Efficacy (LOE) as MNAR (Intent to Treat Sample)

CT-5.12.7 Sensitivity Analysis of MNAR using Placebo Based Imputation in CAPS-5 Total Score (Intent to Treat Sample)

CT-5.12.8 Sensitivity Analysis of MNAR Using Model Based Methods: Shared Parameter Model and Random Coefficient Pattern Mixture Model –OC (Intent to Treat Sample)

CT1-5.1 Summary of Efficacy Results [REDACTED] (Modified Intent to Treat Sample)

CT1-5.2.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - MMRM, UN (Modified Intent to Treat Sample)

CT1-5.2.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - MMRM, TOEPH Empirical (Modified Intent to Treat Sample)

CT1-5.2.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - MMRM, ARH1 Empirical (Modified Intent to Treat Sample)

CT1-5.2.4 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - MMRM, CSH Empirical (Modified Intent to Treat Sample)

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- CT1-5.2.5 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - MMRM, DDFM=SATTERTHWAITE (Modified Intent to Treat Sample)
- CT1-5.2.6.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - LOCF (Modified Intent to Treat Sample)
- CT1-5.2.6.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - OC (Modified Intent to Treat Sample)
- CT1-5.2.7 Summary of Mean Change from Baseline (Day 0) [REDACTED] by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score - OC (Modified Intent to Treat Sample)
- CT1-5.3.1 Summary of Mean Change [REDACTED] to Phase B in CAPS-5 Cluster Subscore - MMRM, UN (Modified Intent to Treat Sample)
- CT1-5.3.2 Summary of Mean Change [REDACTED] to Phase B in CAPS-5 Cluster Subscore - LOCF (Modified Intent to Treat Sample)
- CT1-5.3.3 Summary of Mean Change [REDACTED] to Phase B in CAPS-5 Cluster Subscore - OC (Modified Intent to Treat Sample)
- CT1-5.3.4 Summary of Mean Change from Baseline (Day 0) [REDACTED] in CAPS-5 Cluster Subscore - OC (Modified Intent to Treat Sample)
- CT1-5.4.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinical Global Impression Severity of Illness (CGI-S) Scale - MMRM, UN (Modified Intent to Treat Sample)
- CT1-5.4.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinical Global Impression Severity of Illness (CGI-S) Scale - LOCF (Modified Intent to Treat Sample)
- CT1-5.4.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinical Global Impression Severity of Illness (CGI-S) Scale - OC (Modified Intent to Treat Sample)
- CT1-5.4.4 Summary of Mean Change from Baseline (Day 0) [REDACTED] by Study Week in Clinical Global Impression Severity of Illness (CGI-S) Scale - OC (Modified Intent to Treat Sample)
- CT1-5.5.1 Summary of Proportion of Subjects with a Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Response During Phase B Relative [REDACTED] - LOCF (Modified Intent to Treat Sample)
- CT1-5.5.2 Summary of Proportion of Subjects with a Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Response During Phase B Relative [REDACTED] - OC (Modified Intent to Treat Sample)
- CT1-5.6.1 Summary of Proportion of Subjects with Shift in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Severity Category During Phase B Relative [REDACTED] - LOCF (Modified Intent to Treat Sample)
- CT1-5.6.2 Summary of Proportion of Subjects with Shift in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Severity Category During Phase B Relative [REDACTED] - OC (Modified Intent to Treat Sample)
- CT1-5.7.1 Summary of Mean Change from Baseline (Day 0) to Phase B by Study Week in Symptoms of Trauma Scale (SOTS) Total Score - MMRM, UN (Modified Intent to Treat Sample)
- CT1-5.7.2 Summary of Mean Change from Baseline (Day 0) to Phase B by Study Week in Symptoms of Trauma Scale (SOTS) Total Score - LOCF (Modified Intent to Treat Sample)
- CT1-5.7.3 Summary of Mean Change from Baseline (Day 0) to Phase B by Study Week in Symptoms of Trauma Scale (SOTS) Total Score - OC (Modified Intent to Treat Sample)

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- CT1-5.8.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in PTSD Checklist for DSM-5 (PCL-5) Total Score - MMRM, UN (Modified Intent to Treat Sample)
- CT1-5.8.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in PTSD Checklist for DSM-5 (PCL-5) Total Score - LOCF (Modified Intent to Treat Sample)
- CT1-5.8.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in PTSD Checklist for DSM-5 (PCL-5) Total Score - OC (Modified Intent to Treat Sample)
- CT1-5.8.4 Summary of Mean Change from Baseline (Day 0) [REDACTED] by Study Week in PTSD Checklist for DSM-5 (PCL-5) Total Score - OC (Modified Intent to Treat Sample)
- CT1-5.9.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Hospital Anxiety and Depression Scale (HADS) Subscale Score - MMRM, UN (Modified Intent to Treat Sample)
- CT1-5.9.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Hospital Anxiety and Depression Scale (HADS) Subscale Score - LOCF (Modified Intent to Treat Sample)
- CT1-5.9.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in Hospital Anxiety and Depression Scale (HADS) Subscale Score - OC (Modified Intent to Treat Sample)
- CT1-5.9.4 Summary of Mean Change from Baseline (Day 0) [REDACTED] by Study Week in Hospital Anxiety and Depression Scale (HADS) Subscale Score - OC (Modified Intent to Treat Sample)
- CT-6.1.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup of Females - MMRM (Intent to Treat Sample)
- CT-6.1.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup of Males - MMRM (Intent to Treat Sample)
- CT-6.2.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup of Whites - MMRM (Intent to Treat Sample)
- CT-6.2.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup of All Other Races - MMRM (Intent to Treat Sample)
- CT-6.3.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects <55 Years of Age - MMRM (Intent to Treat Sample)
- CT-6.3.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects ≥55 Years of Age or Older - MMRM (Intent to Treat Sample)
- CT-6.4.1.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects with <20% Improvement [REDACTED] and CAPS-5 Total Score at Least 27 at Week 1 - MMRM (Intent to Treat Sample)
- CT-6.4.1.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects with ≥20% Improvement [REDACTED] or CAPS-5 Total Score <27 at Week 1 - MMRM (Intent to Treat Sample)
- CT-6.4.2.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects with <25% Improvement [REDACTED] and CAPS-5 Total Score at Least 27 at Week 1 - MMRM (Intent to Treat Sample)
- CT-6.4.2.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects with ≥25% Improvement [REDACTED] or CAPS-5 Total Score <27 at Week 1 - MMRM (Intent to Treat Sample)

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- CT-6.4.3.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects with <30% Improvement [REDACTED] and CAPS-5 Total Score at Least 27 at Week 1 - MMRM (Intent to Treat Sample)
- CT-6.4.3.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects with ≥30% Improvement [REDACTED] or CAPS-5 Total Score <27 at Week 1 - MMRM (Intent to Treat Sample)
- CT-6.5.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup with Combat-related Trauma - MMRM (Intent to Treat Sample)
- CT-6.5.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup without Combat-related Trauma - MMRM (Intent to Treat Sample)
- CT-6.6.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup with Psychosocial Support at Baseline - MMRM (Intent to Treat Sample)
- CT-6.6.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup without Psychosocial Support at Baseline - MMRM (Intent to Treat Sample)
- CT-6.7.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup with Previous Pharmacological Treatment Intervention for PTSD - MMRM (Intent to Treat Sample)
- CT-6.7.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup without Previous Pharmacological Treatment Intervention for PTSD - MMRM (Intent to Treat Sample)
- CT-6.8.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup with Use of Wearable Device - MMRM (Intent to Treat Sample)
- CT-6.8.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup without Use of Wearable Device - MMRM (Intent to Treat Sample)
- CT-6.9.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup with <5 Years Since Index Traumatic Event – MMRM (Intent to Treat Sample)
- CT-6.9.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup with ≥5-<10 Years Since Index Traumatic Event – MMRM (Intent to Treat Sample)
- CT-6.9.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup with ≥10 Years Since Index Traumatic Event – MMRM (Intent to Treat Sample)
- CT-6.10.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects <30 Years of Age – MMRM (Intent to Treat Sample)
- CT-6.10.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects ≥30-<40 Years of Age or Older – MMRM (Intent to Treat Sample)
- CT-6.10.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects 40 Years of Age or Older – MMRM (Intent to Treat Sample)

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- CT1-6.1.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup of Females - MMRM (Modified Intent to Treat Sample)
- CT1-6.1.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup of Males - MMRM (Modified Intent to Treat Sample)
- CT1-6.2.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup of Whites - MMRM (Modified Intent to Treat Sample)
- CT1-6.2.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup of All Other Races - MMRM (Modified Intent to Treat Sample)
- CT1-6.3.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in SubjeCT1s <55 Years of Age - MMRM (Modified Intent to Treat Sample)
- CT1-6.3.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in SubjeCT1s ≥55 Years of Age or Older - MMRM (Modified Intent to Treat Sample)
- CT1-6.4.1.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in SubjeCT1s with <20% Improvement [REDACTED] and CAPS-5 Total Score at Least 27 at Week 1 - MMRM (Modified Intent to Treat Sample)
- CT1-6.4.1.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects with ≥20% Improvement [REDACTED] or CAPS-5 Total Score <27 at Week 1 - MMRM (Modified Intent to Treat Sample)
- CT1-6.4.2.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects with <25% Improvement [REDACTED] and CAPS-5 Total Score at Least 27 at Week 1 - MMRM (Modified Intent to Treat Sample)
- CT1-6.4.2.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects with ≥25% Improvement [REDACTED] or CAPS-5 Total Score <27 at Week 1 - MMRM (Modified Intent to Treat Sample)
- CT1-6.5.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup with Combat-related Trauma - MMRM (Modified Intent to Treat Sample)
- CT1-6.5.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup without Combat-related Trauma - MMRM (Modified Intent to Treat Sample)
- CT1-6.6.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup with Psychosocial Support at Baseline - MMRM (Modified Intent to Treat Sample)
- CT1-6.6.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup without Psychosocial Support at Baseline - MMRM (Modified Intent to Treat Sample)
- CT1-6.7.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup with Previous Pharmacological Treatment Intervention for PTSD - MMRM (Modified Intent to Treat Sample)
- CT1-6.7.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup without Previous Pharmacological Treatment Intervention for PTSD - MMRM (Modified Intent to Treat Sample)

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CT1-6.8.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup with Use of Wearable Device - MMRM (Modified Intent to Treat Sample)

CT1-6.8.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup without Use of Wearable Device - MMRM (Modified Intent to Treat Sample)

CT1-6.9.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup with <5 Years Since Index Traumatic Event – MMRM (Modified Intent to Treat Sample)

CT1-6.9.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup with >=5-<10 Years Since Index Traumatic Event – MMRM (Modified Intent to Treat Sample)

CT1-6.9.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in the Subgroup with >=10 Years Since Index Traumatic Event – MMRM (Modified Intent to Treat Sample)

CT1-6.10.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects <30 Years of Age – MMRM (Modified Intent to Treat Sample)

CT1-6.10.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects >=30-<40 Years of Age or Older – MMRM (Modified Intent to Treat Sample)

CT1-6.10.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) Total Score in Subjects 40 Years of Age or Older – MMRM (Modified Intent to Treat Sample)

CT-7.1 Extent of Exposure to Study Medication During Phase B (Safety Sample)

CT-7.2.1 Number and Percentage of Subjects Receiving Brexpiprazole and Mean and Range of Average Daily Dose in Phase B (Safety Sample)

CT-7.2.2 Number and Percentage of Subjects Receiving Sertraline and Mean and Range of Average Daily Dose in Phase B (Safety Sample)

CT-8.1 Adverse Events (Safety Sample)

CT-8.2.1 Incidence of TEAEs During Phase B by System Organ Class and MedDRA Preferred Term (Safety Sample)

CT-8.2.2 Incidence of TEAEs During Phase B by System Organ Class, MedDRA Preferred Term and Severity (Safety Sample)

CT-8.2.3 Incidence of TEAE During Phase B of at Least 5% in Any Brexpiprazole or Sertraline Group and Greater Than Placebo by System Organ Class and MedDRA Preferred Term (Safety Sample)

CT-8.2.4 Incidence of TEAEs During Phase B by System Organ Class and MedDRA Preferred Term, by Sex (Safety Sample)

CT-8.2.5 Incidence of TEAEs During Phase B by System Organ Class and MedDRA Preferred Term, by Race (Safety Sample)

CT-8.2.6 Incidence of TEAEs During Phase B by System Organ Class and MedDRA Preferred Term, by Age (Safety Sample)

CT-8.2.7 Incidence of Non-Serious TEAE During Phase B of at Least 5% in Any Brexpiprazole or Sertraline Group and Greater Than Placebo by System Organ Class and MedDRA Preferred Term (Safety Sample)

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- CT-8.2.8 Incidence of TEAE During Phase B of at Least 2% in Any Brexipiprozole or Sertraline Group and Greater Than Placebo by System Organ Class and MedDRA Preferred Term (Safety Sample)
- CT-8.2.9 Occurrence (Number of Events) of Serious Treatment-Emergent Adverse Events by System Organ Class and MedDRA Preferred Term (Safety Sample)
- CT-8.2.10 Incidence and Occurrence (Number of Events) of All Treatment-Emergent Adverse Events Greater Than or Equal To 5% in Any Treatment Group by System Organ Class and MedDRA Preferred Term (Safety Sample)
- CT-8.2.11 Incidence and Occurrence (Number of Events) of Non-Serious Treatment-Emergent Adverse Events Greater Than or Equal To 5% in Any Treatment Group by System Organ Class and MedDRA Preferred Term (Safety Sample)
- CT-8.3.1 Incidence of Potentially Drug-Related TEAEs During Phase B by System Organ Class and MedDRA Preferred Term (Safety Sample)
- CT-8.3.2 Incidence of Potentially Drug-Related TEAEs During Phase B by System Organ Class, MedDRA Preferred Term and Severity (Safety Sample)
- CT-8.4 Incidence of Deaths Due to TEAEs During Phase B by System Organ Class and MedDRA Preferred Term (Safety Sample)
- CT-8.5.1 Incidence of Serious TEAEs During Phase B by System Organ Class and MedDRA Preferred Term (Safety Sample)
- CT-8.5.2 Incidence of Serious TEAEs During Phase B by System Organ Class, MedDRA Preferred Term and Severity (Safety Sample)
- CT-8.6.1 Incidence of TEAEs Resulting in Discontinuation from Study Medication During Phase B by System Organ Class and MedDRA Preferred Term (Safety Sample)
- CT-8.6.2 Incidence of TEAEs Resulting in Discontinuation from Study Medication During Phase B by System Organ Class, MedDRA Preferred Term and Severity (Safety Sample)
- CT-8.7.1 Incidence of TE EPS-related AEs During Phase B by EPS Category and MedDRA Preferred Term (Safety Sample)
- CT-8.7.2 Incidence of Onset of Akathisia Adverse Event by Week During Phase B (Safety Sample)
- CT-9.1 Listing of Deaths
- CT-9.2 Listing of Serious Adverse Events
- CT-9.3.1 Listing of Discontinuations from Study Medication Due to Adverse Events During Phase B
- CT-9.3.2 Listing of Discontinuations from Study Medication Due to Adverse Events [REDACTED]
- CT-10.1 Criteria for Laboratory Test Values with Potential Clinical Relevance
- CT-10.2.1 Listing of Laboratory Test Values with Potential Clinical Relevance During Phase B by Subject (Safety Sample)
- CT-10.2.2 Listing of Laboratory Test Values with Potential Clinical Relevance During Phase B by Test (Safety Sample)
- CT-10.2.3 Incidence of Laboratory Test Values with Potential Clinical Relevance During Phase B (Safety Sample)
- CT-10.3.1 Mean Change [REDACTED] in Clinical Laboratory Test Results - Serum Chemistry (Safety Sample)
- CT-10.3.2 Mean Change [REDACTED] in Clinical Laboratory Test Results - Hematology (Safety Sample)
- CT-10.3.3 Mean Change [REDACTED] in Clinical Laboratory Test Results - Urinalysis (Safety Sample)

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- CT-10.3.4 Mean Change [REDACTED] in Clinical Laboratory Test Results – Prolactin, by Sex (Safety Sample)
- CT-10.4.1 Incidence of Laboratory Test Values with Potential Clinical Relevance During Phase B - Prolactin (Safety Sample)
- CT-10.4.2 Listing of Laboratory Test Values with Potential Clinical Relevance During Phase B - Prolactin (Safety Sample)
- CT-10.5.1.1 Incidence of Treatment-Emergent Significant Change in Lipids During Phase B (Safety Sample)
- CT-10.5.1.2 Listing of Treatment-Emergent Significant Change in Lipids During Phase B (Safety Sample)
- CT-10.5.2.1 Incidence of Treatment-Emergent Significant Change in Glucose During Phase B (Safety Sample)
- CT-10.5.2.2 Listing of Treatment-Emergent Significant Change in Glucose During Phase B (Safety Sample)
- CT-10.5.3.1 Incidence of Treatment-Emergent Metabolic Syndrome During Phase B (Safety Sample)
- CT-10.5.3.2 Listing of Treatment-Emergent Metabolic Syndrome During Phase B (Safety Sample)
- CT-10.6 Incidence of Potentially Liver Injury Related Laboratory Test Abnormalities During Phase B (Safety Sample)
- CT-10.7 Listing of Potentially Liver Injury Related Laboratory Test Abnormalities During Phase B (Safety Sample)

- CT-11.1 Criteria for Potentially Clinically Relevant Abnormalities in Vital Signs
- CT-11.2.1 Listing of Potentially Clinically Relevant Abnormalities in Vital Signs During Phase B (Safety Sample)
- CT-11.2.2 Incidence of Potentially Clinically Relevant Abnormalities in Vital Signs During Phase B (Safety Sample)
- CT-11.2.3 Mean Change from [REDACTED] in Vital Signs During Phase B (Safety Sample)
- CT-11.3.1 Listing of Potentially Clinically Relevant Abnormalities in Vital Signs [REDACTED] (Safety Sample)
- CT-11.3.2 Incidence of Potentially Clinically Relevant Abnormalities in Vital Signs [REDACTED] (Safety Sample)
- CT-11.3.3 Mean Change from Baseline in Vital Signs [REDACTED] (Safety Sample)

- CT-12.1.1 Criteria for Potentially Clinically Relevant Abnormalities in ECG Evaluations
- CT-12.1.2 ECG Diagnosis Mapping for Potentially Clinically Relevant Electrocardiogram Abnormalities
- CT-12.2.1 Listing of Potentially Clinically Relevant Abnormalities in ECG Evaluations During Phase B (Safety Sample)
- CT-12.2.2 Incidence of Potentially Clinically Relevant Changes in ECG Evaluations During Phase B (Safety Sample)
- CT-12.2.3 Mean Change [REDACTED] in Electrocardiogram Results During Phase B (Safety Sample)
- CT-12.3.1 Listing of Categorical Changes in QT/QTc During Phase B (Safety Sample)
- CT-12.3.2 Incidence of Categorical Changes in QT/QTc During Phase B (Safety Sample)

- CT-13.1 Summary of Mean Change from Baseline (Day 0) to Phase B by Study Week in Simpson-Angus Scale (SAS) Total Score (Safety Sample)
- CT-13.2 Summary of Mean Change from Baseline (Day 0) to Phase B by Study Week in Abnormal Involuntary Movement Scale (AIMS) Total Score and Item Scores 8, 9 and 10 (Safety Sample)

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CT-13.3.1 Summary of Mean Change from Baseline (Day 0) to Phase B by Study Week in Barnes Akathisia Rating Scale (BARS) Global Clinical Assessment of Akathisia (Safety Sample)

CT-13.3.2 Incidence of Barnes Akathisia Rating Scale (BARS) Global Clinical Assessment of Akathisia During Phase B (Safety Sample)

CT-14.1.1 Columbia-Suicide Severity Rating Scale(C-SSRS) During Phase B, Suicidality (Safety Sample)

CT-14.1.2 Columbia-Suicide Severity Rating Scale(C-SSRS) During Phase B, Suicidal Behavior by Type (Safety Sample)

CT-14.1.3 Columbia-Suicide Severity Rating Scale(C-SSRS) During Phase B, Suicidal Ideation by Type (Safety Sample)

CT-14.1.4 Columbia-Suicide Severity Rating Scale(C-SSRS) During Phase B, Treatment Emergent Suicidal Behavior and Ideation (Safety Sample)

CT-14.1.5 Columbia-Suicide Severity Rating Scale (C-SSRS) – Listing of Treatment Emergent Suicidal Ideation During Phase B (Safety Sample)

CT-14.1.6 Columbia-Suicide Severity Rating Scale (C-SSRS) – Listing of Treatment Emergent Suicidal Behavior During Phase B (Safety Sample)

CT-14.1.7 Columbia-Suicide Severity Rating Scale (C-SSRS) – Listing of Treatment Emergent Serious Suicidal Ideation During Phase B (Safety Sample)

CT-14.1.8 Columbia-Suicide Severity Rating Scale (C-SSRS) – Listing of Worsening Suicidal Ideation During Phase B (Safety Sample)

CT-14.2.1 Columbia-Suicide Severity Rating Scale(C-SSRS) [REDACTED] Suicidality (Safety Sample)

CT-14.2.2 Columbia-Suicide Severity Rating Scale(C-SSRS) [REDACTED], Suicidal Behavior by Type (Safety Sample)

CT-14.2.3 Columbia-Suicide Severity Rating Scale(C-SSRS) [REDACTED] Suicidal Ideation by Type (Safety Sample)

CT-14.2.4 Columbia-Suicide Severity Rating Scale(C-SSRS) [REDACTED] Treatment Emergent Suicidal Behavior and Ideation (Safety Sample)

CT-14.2.5 Columbia-Suicide Severity Rating Scale (C-SSRS) – Listing of Treatment Emergent Suicidal Ideation [REDACTED] (Safety Sample)

CT-14.2.6 Columbia-Suicide Severity Rating Scale (C-SSRS) – Listing of Treatment Emergent Suicidal Behavior [REDACTED] (Safety Sample)

CT-14.2.7 Columbia-Suicide Severity Rating Scale (C-SSRS) – Listing of Treatment Emergent Serious Suicidal Ideation [REDACTED] (Safety Sample)

CT-14.2.8 Columbia-Suicide Severity Rating Scale (C-SSRS) – Listing of Worsening Suicidal Ideation [REDACTED] (Safety Sample)

CT-15.1.1 Summary of Mean Change [REDACTED] to Phase B by Study Week in Body Weight (kg) (Safety Sample)

CT-15.1.2 Summary of Proportion of Patients with Potentially Clinically Relevant Weight Gain or Weight Loss During Phase B (Safety Sample)

CT-15.2 Summary of Mean Change [REDACTED] to Phase B by Study Week in Waist Circumference (cm) (Safety Sample)

CT-15.3 Summary of Mean Change [REDACTED] to Phase B by Study Week in BMI (kg/m2) (Safety Sample)





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BREXPIRAZOLE
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STAT-1.1
 Adjusted Mean Change [REDACTED] in CAPS-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

CAPS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹				
CAPSW-INTRUSIVE MEMORIES SEVERITY	77	2.22	-1.25	69	2.03	-1.03	75	2.16	-0.71	78	2.00	-0.99	BREX+SERT VS PLACEBO	-0.26	0.2237	-0.20
													BREX+SERT VS SERT	-0.54	0.0137	-0.40
													BREX+SERT VS BREX	-0.23	0.3141	-0.17
													BREX VS PLACEBO	-0.03	0.8871	-0.02
													SERT VS PLACEBO	0.28	0.1936	0.21
CAPSW-DISTRESSI NG DREAMS SEVERITY	77	1.19	-0.64	69	1.42	-0.60	75	1.63	-0.48	78	1.38	-0.57	BREX+SERT VS PLACEBO	-0.07	0.7364	-0.05
													BREX+SERT VS SERT	-0.15	0.4517	-0.12
													BREX+SERT VS BREX	-0.03	0.8745	-0.03
													BREX VS PLACEBO	-0.03	0.8738	-0.03
													SERT VS PLACEBO	0.09	0.6670	0.07
CAPSW-DISSOCIAT IVE REACTIONS SEVERITY	77	0.81	-0.62	69	0.67	-0.38	75	0.80	-0.29	78	0.82	-0.48	BREX+SERT VS PLACEBO	-0.14	0.3462	-0.15
													BREX+SERT VS SERT	-0.33	0.0335	-0.35
													BREX+SERT VS BREX	-0.24	0.1331	-0.25
													BREX VS PLACEBO	0.10	0.5279	0.10
													SERT VS PLACEBO	0.19	0.2205	0.20

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, (POOLED) STUDY CENTER, TYPE OF TRAUMA, VISIT, TREATMENT BY VISIT AND BASELINE BY

FILE: caps_itema.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/caps_item.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-1.1 FINAL

BREXPIRAZOLE
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Adjusted Mean Change [REDACTED] STAT-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

CAPS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
CAPSW-CUED PSYCHOLOGICAL DISTRESS SEVERITY	77	2.17	-1.14	69	1.90	-0.98	75	2.15	-0.84	78	2.17	-0.86	BREX+SERT VS PLACEBO	-0.29	0.1627	-0.23
													BREX+SERT VS SERT	-0.30	0.1494	-0.23
													BREX+SERT VS BREX	-0.16	0.4608	-0.12
													BREX VS PLACEBO	-0.13	0.5654	-0.10
													SERT VS PLACEBO	0.02	0.9397	0.01
CAPSW-CUED PSYCHOLOGICAL REACTION SEVERITY	77	2.00	-1.26	69	1.84	-1.16	75	2.07	-0.54	78	2.05	-0.62	BREX+SERT VS PLACEBO	-0.64	0.0021	-0.50
													BREX+SERT VS SERT	-0.72	0.0007	-0.56
													BREX+SERT VS BREX	-0.10	0.6630	-0.07
													BREX VS PLACEBO	-0.55	0.0125	-0.42
													SERT VS PLACEBO	0.08	0.7018	0.06
CAPSW-AVOID MEM THGHTS FEELINGS SEVERITY	77	2.38	-1.17	69	2.12	-0.70	75	2.41	-0.65	78	2.33	-0.86	BREX+SERT VS PLACEBO	-0.31	0.1417	-0.24
													BREX+SERT VS SERT	-0.52	0.0162	-0.39

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, (POOLED) STUDY CENTER, TYPE OF TRAUMA, VISIT, TREATMENT BY VISIT AND BASELINE BY

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 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-1.1 FINAL

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BREXPIRAZOLE
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Adjusted Mean Change [REDACTED] STAT-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

CAPS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹				
CAPSW-AVOID MEM THGHTS FEELNGS SEVERITY													BREX+SERT VS BREX	-0.47	0.0377	-0.35
													BREX VS PLACEBO	0.16	0.4737	0.12
													SERT VS PLACEBO	0.21	0.3233	0.16
CAPSW-AVOID EXTERNL REMINDRS SEVERITY	77	2.13	-0.95	69	2.03	-0.71	75	2.27	-0.65	78	2.22	-0.75	BREX+SERT VS PLACEBO	-0.20	0.3393	-0.15
													BREX+SERT VS SERT	-0.30	0.1556	-0.23
													BREX+SERT VS BREX	-0.24	0.2772	-0.18
													BREX VS PLACEBO	0.04	0.8505	0.03
													SERT VS PLACEBO	0.10	0.6244	0.08
CAPSW-INABLT RECAL ASPCT EVNT SEVERITY	77	0.71	-0.25	69	0.78	-0.21	75	0.55	-0.17	78	0.55	-0.25	BREX+SERT VS PLACEBO	-0.00	0.9956	-0.00
													BREX+SERT VS SERT	-0.08	0.5116	-0.11
													BREX+SERT VS BREX	-0.04	0.7358	-0.06
													BREX VS PLACEBO	0.04	0.7377	0.06
													SERT VS PLACEBO	0.07	0.5087	0.11

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, (POOLED) STUDY CENTER, TYPE OF TRAUMA, VISIT, TREATMENT BY VISIT AND BASELINE BY

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Adjusted Mean Change [REDACTED] in CAPS-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

CAPS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN'S D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹				
CAPSW-EXGGRTD NEG BELIFS EXPTNS SEVERITY	77	2.30	-1.02	69	2.13	-0.54	75	2.27	-0.79	78	2.05	-0.50	BREX+SERT VS PLACEBO	-0.52	0.0074	-0.43
													BREX+SERT VS SERT	-0.22	0.2521	-0.19
													BREX+SERT VS BREX	-0.48	0.0193	-0.39
													BREX VS PLACEBO	-0.04	0.8469	-0.03
													SERT VS PLACEBO	-0.30	0.1285	-0.25
CAPSW-DIST COGTNS LEADNG BLAME SEVERITY	77	1.81	-0.86	69	1.41	-0.79	75	1.89	-0.69	78	1.38	-0.59	BREX+SERT VS PLACEBO	-0.27	0.1639	-0.22
													BREX+SERT VS SERT	-0.17	0.3946	-0.14
													BREX+SERT VS BREX	-0.07	0.7477	-0.05
													BREX VS PLACEBO	-0.21	0.3088	-0.17
													SERT VS PLACEBO	-0.11	0.5918	-0.09
CAPSW-PRSISTNT NEG EMOTNL STATE SEVERITY	77	2.09	-0.99	69	2.23	-0.84	75	2.28	-0.86	78	2.10	-0.53	BREX+SERT VS PLACEBO	-0.46	0.0183	-0.38
													BREX+SERT VS SERT	-0.13	0.5152	-0.11
													BREX+SERT VS BREX	-0.14	0.4877	-0.12
													BREX VS PLACEBO	-0.32	0.1222	-0.26
													SERT VS PLACEBO	-0.33	0.0918	-0.27

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BREXPIRAZOLE
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Adjusted Mean Change [REDACTED] STAT-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

CAPS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹				
CAPSW-DIMISHD INTRST ACTVTIES SEVERITY	77	2.01	-1.09	69	1.97	-0.54	75	2.04	-0.55	78	2.05	-0.62	BREX+SERT VS PLACEBO	-0.48	0.0195	-0.38
													BREX+SERT VS SERT	-0.54	0.0087	-0.43
													BREX+SERT VS BREX	-0.55	0.0112	-0.42
													BREX VS PLACEBO	0.08	0.7236	0.06
													SERT VS PLACEBO	0.07	0.7334	0.06
CAPSW-DETACHMNT ESTRNGMNT OTHSR SEVERITY	77	2.30	-0.87	69	2.00	-0.73	75	2.25	-0.63	78	2.35	-0.46	BREX+SERT VS PLACEBO	-0.41	0.0519	-0.31
													BREX+SERT VS SERT	-0.25	0.2515	-0.19
													BREX+SERT VS BREX	-0.15	0.5203	-0.11
													BREX VS PLACEBO	-0.27	0.2344	-0.20
													SERT VS PLACEBO	-0.17	0.4383	-0.13
CAPSW-PRISISTNT INAB EXP POSTVE SEVERITY	77	1.83	-0.91	69	1.62	-0.42	75	1.80	-0.54	78	1.78	-0.38	BREX+SERT VS PLACEBO	-0.53	0.0068	-0.44
													BREX+SERT VS SERT	-0.38	0.0606	-0.31
													BREX+SERT VS BREX	-0.49	0.0185	-0.39
													BREX VS PLACEBO	-0.04	0.8497	-0.03

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Adjusted Mean Change [REDACTED] STAT-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

CAPS Line Items	Brex+Sert ²			Brex ²			Sert ²			Placebo			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN'S D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹				
CAPSW-PRISISTNT INAB EXP POSTVE SEVERITY													SERT VS PLACEBO	-0.16	0.4225	-0.13
CAPSW-IRRITBLE BEHAV ANGRY SEVERITY	77	1.55	-0.50	69	1.46	-0.58	75	1.49	-0.50	78	1.53	-0.37	BREX+SERT VS PLACEBO	-0.13	0.4921	-0.11
													BREX+SERT VS SERT	-0.00	0.9896	-0.00
													BREX+SERT VS BREX	0.09	0.6777	0.07
													BREX VS PLACEBO	-0.22	0.2837	-0.18
													SERT VS PLACEBO	-0.13	0.5028	-0.11
CAPSW-RECKLS SELF DESTR BEHAV SEVERITY	77	0.31	-0.11	69	0.29	-0.11	75	0.25	-0.17	78	0.32	-0.10	BREX+SERT VS PLACEBO	-0.02	0.8469	-0.03
													BREX+SERT VS SERT	0.06	0.5354	0.10
													BREX+SERT VS BREX	-0.00	0.9591	-0.01
													BREX VS PLACEBO	-0.01	0.8960	-0.02
													SERT VS PLACEBO	-0.07	0.4115	-0.13
CAPSW-HYPERVIGI LANCE SEVERITY	77	2.44	-0.78	69	2.19	-0.37	75	2.25	-0.66	78	2.26	-0.36	BREX+SERT VS PLACEBO	-0.42	0.0237	-0.37
													BREX+SERT VS SERT	-0.11	0.5439	-0.10

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Adjusted Mean Change [REDACTED] STAT-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

CAPS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN's D EFFECT SIZE
	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹				
CAPSW-HYPERVIGI LANCSEVERITY													BREX+SERT VS BREX	-0.41	0.0382	-0.35
													BREX VS PLACEBO	-0.01	0.9537	-0.01
													SERT VS PLACEBO	-0.31	0.0996	-0.27
CAPSW-EXAGGERAT D STRTLE RESPNSE SEVERITY	77	1.30	-0.49	69	1.36	-0.46	75	1.47	-0.47	78	1.23	-0.41	BREX+SERT VS PLACEBO	-0.09	0.6425	-0.07
													BREX+SERT VS SERT	-0.02	0.9011	-0.02
													BREX+SERT VS BREX	-0.03	0.8656	-0.03
													BREX VS PLACEBO	-0.05	0.7881	-0.04
													SERT VS PLACEBO	-0.06	0.7373	-0.05
CAPSW-PRBLMS WTH CONCENTRATION SEVERITY	77	2.00	-0.73	69	2.13	-0.58	75	1.85	-0.61	78	2.01	-0.55	BREX+SERT VS PLACEBO	-0.18	0.3372	-0.15
													BREX+SERT VS SERT	-0.12	0.5197	-0.10
													BREX+SERT VS BREX	-0.14	0.4690	-0.12
													BREX VS PLACEBO	-0.03	0.8586	-0.03
													SERT VS PLACEBO	-0.06	0.7634	-0.05

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Adjusted Mean Change [REDACTED] STAT-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

CAPS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹				
CAPSW-SLEEP DISTURBANCE SEVERITY	77	2.18	-0.69	69	2.30	-0.84	75	2.63	-0.34	78	2.55	-0.33	BREX+SERT VS PLACEBO	-0.37	0.0850	-0.28
													BREX+SERT VS SERT	-0.36	0.1024	-0.27
													BREX+SERT VS BREX	0.15	0.5147	0.11
													BREX VS PLACEBO	-0.51	0.0212	-0.38
													SERT VS PLACEBO	-0.01	0.9560	-0.01
CAPSW-SUBJECTIV E DISTRESS SEVERITY	77	2.48	-0.89	69	2.38	-0.59	75	2.51	-0.59	78	2.33	-0.60	BREX+SERT VS PLACEBO	-0.29	0.0306	-0.35
													BREX+SERT VS SERT	-0.30	0.0242	-0.37
													BREX+SERT VS BREX	-0.30	0.0356	-0.35
													BREX VS PLACEBO	0.01	0.9468	0.01
													SERT VS PLACEBO	0.02	0.9004	0.02
CAPSW-IMPAIRMNT SOCIAL FUNCTNG SEVERITY	77	2.49	-1.19	69	2.22	-0.81	75	2.45	-0.81	78	2.37	-0.61	BREX+SERT VS PLACEBO	-0.58	0.0003	-0.58
													BREX+SERT VS SERT	-0.38	0.0213	-0.38
													BREX+SERT VS BREX	-0.37	0.0299	-0.36
													BREX VS PLACEBO	-0.21	0.2177	-0.20
													SERT VS PLACEBO	-0.20	0.2102	-0.20

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Adjusted Mean Change [REDACTED] STAT-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

CAPS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
CAPSW-IMPAIRMENT OCCUP FUNCTIONING SEVERITY	77	2.22	-0.82	69	1.96	-0.64	75	2.21	-0.69	78	2.18	-0.54	BREX+SERT VS PLACEBO	-0.28	0.1021	-0.26
													BREX+SERT VS SERT	-0.13	0.4576	-0.12
													BREX+SERT VS BREX	-0.19	0.3116	-0.17
													BREX VS PLACEBO	-0.10	0.5921	-0.09
													SERT VS PLACEBO	-0.15	0.3823	-0.14
CAPSW-SEVERITY SUBTOTAL G	77	7.19	-2.91	69	6.55	-1.95	75	7.17	-2.09	78	6.88	-1.70	BREX+SERT VS PLACEBO	-1.21	0.0015	-0.52
													BREX+SERT VS SERT	-0.82	0.0336	-0.35
													BREX+SERT VS BREX	-0.96	0.0171	-0.40
													BREX VS PLACEBO	-0.25	0.5240	-0.11
													SERT VS PLACEBO	-0.39	0.3037	-0.17
CAPSW-GLOBAL VALIDITY	77	0.22	0.03	69	0.16	-0.01	75	0.17	-0.08	78	0.09	0.00	BREX+SERT VS PLACEBO	0.02	0.6452	0.07
													BREX+SERT VS SERT	0.11	0.0328	0.35
													BREX+SERT VS BREX	0.04	0.4345	0.13
													BREX VS PLACEBO	-0.02	0.7219	-0.06
													SERT VS PLACEBO	-0.08	0.0850	-0.28

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Adjusted Mean Change [REDACTED] STAT-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

CAPS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
CAPSW-GLOBAL SEVERITY	77	2.55	-0.87	69	2.41	-0.69	75	2.53	-0.57	78	2.38	-0.58	BREX+SERT VS PLACEBO	-0.29	0.0481	-0.32
													BREX+SERT VS SERT	-0.30	0.0417	-0.33
													BREX+SERT VS BREX	-0.18	0.2402	-0.20
													BREX VS PLACEBO	-0.11	0.4809	-0.12
													SERT VS PLACEBO	0.01	0.9241	0.02
CAPSW-GLOBAL IMPROVEMENT	77	3.42	-1.30	69	3.25	-0.99	75	3.40	-0.80	78	3.33	-0.92	BREX+SERT VS PLACEBO	-0.38	0.0416	-0.33
													BREX+SERT VS SERT	-0.50	0.0094	-0.42
													BREX+SERT VS BREX	-0.31	0.1261	-0.25
													BREX VS PLACEBO	-0.08	0.7004	-0.06
													SERT VS PLACEBO	0.12	0.5373	0.10
CAPSW-DEPERSONA LIZATION SEVERITY	77	0.27	-0.27	69	0.29	-0.14	75	0.28	-0.24	78	0.24	-0.22	BREX+SERT VS PLACEBO	-0.05	0.4467	-0.12
													BREX+SERT VS SERT	-0.03	0.6785	-0.07
													BREX+SERT VS BREX	-0.13	0.0561	-0.32
													BREX VS PLACEBO	0.08	0.2217	0.20
													SERT VS PLACEBO	-0.02	0.7365	-0.05

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Adjusted Mean Change [REDACTED] in CAPS-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

CAPS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
CAPSW-DEREALIZA TION SEVERITY	77	0.29	-0.23	69	0.29	-0.12	75	0.21	-0.13	78	0.23	-0.23	BREX+SERT VS PLACEBO	0.00	0.9549	0.01
													BREX+SERT VS SERT	-0.10	0.1687	-0.22
													BREX+SERT VS BREX	-0.11	0.1528	-0.24
													BREX VS PLACEBO	0.12	0.1337	0.25
													SERT VS PLACEBO	0.11	0.1472	0.24
CAPSW-SEVERITY SUBTOTAL DISS	77	0.56	-0.50	69	0.58	-0.26	75	0.49	-0.37	78	0.47	-0.45	BREX+SERT VS PLACEBO	-0.05	0.6680	-0.07
													BREX+SERT VS SERT	-0.13	0.2612	-0.18
													BREX+SERT VS BREX	-0.24	0.0416	-0.34
													BREX VS PLACEBO	0.19	0.0954	0.28
													SERT VS PLACEBO	0.08	0.4740	0.12
CAPS-5 SUBSCALE B TOTAL SEVERITY SCORE	77	8.39	-4.93	69	7.86	-4.17	75	8.80	-2.87	78	8.42	-3.55	BREX+SERT VS PLACEBO	-1.38	0.0564	-0.31
													BREX+SERT VS SERT	-2.06	0.0058	-0.45
													BREX+SERT VS BREX	-0.76	0.3235	-0.16
													BREX VS PLACEBO	-0.63	0.4075	-0.14
													SERT VS PLACEBO	0.67	0.3560	0.15

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, (POOLED) STUDY CENTER, TYPE OF TRAUMA, VISIT, TREATMENT BY VISIT AND BASELINE BY

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BREXPIRAZOLE
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Adjusted Mean Change [REDACTED] STAT-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

CAPS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹		P-VALUE ¹		
CAPS-5 SUBSCALE C TOTAL SEVERITY SCORE	77	4.51	-2.13	69	4.14	-1.37	75	4.68	-1.33	78	4.55	-1.60	BREX+SERT VS PLACEBO	-0.52	0.1376	-0.24
													BREX+SERT VS SERT	-0.79	0.0273	-0.36
													BREX+SERT VS BREX	-0.76	0.0440	-0.34
													BREX VS PLACEBO	0.23	0.5296	0.10
													SERT VS PLACEBO	0.27	0.4408	0.12
CAPS-5 SUBSCALE D TOTAL SEVERITY SCORE	77	13.05	-6.12	69	12.14	-3.99	75	13.08	-4.30	78	12.27	-3.32	BREX+SERT VS PLACEBO	-2.79	0.0007	-0.55
													BREX+SERT VS SERT	-1.82	0.0285	-0.36
													BREX+SERT VS BREX	-2.13	0.0137	-0.41
													BREX VS PLACEBO	-0.67	0.4296	-0.13
													SERT VS PLACEBO	-0.98	0.2317	-0.19
CAPS-5 SUBSCALE E TOTAL SEVERITY SCORE	77	9.78	-3.33	69	9.74	-2.92	75	9.95	-2.77	78	9.90	-2.14	BREX+SERT VS PLACEBO	-1.19	0.0366	-0.34
													BREX+SERT VS SERT	-0.56	0.3325	-0.16

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Adjusted Mean Change [REDACTED] in CAPS-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

CAPS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹		P-VALUE ¹		
CAPS-5 SUBSCALE E TOTAL SEVERITY SCORE													BREX+SERT VS BREX	-0.40	0.5043	-0.11
													BREX VS PLACEBO	-0.79	0.1857	-0.22
													SERT VS PLACEBO	-0.63	0.2708	-0.18
CAPS-5 TOTAL SEVERITY SCORE	77	35.73	-16.4	69	33.88	-12.2	75	36.51	-11.4	78	35.14	-10.5	BREX+SERT VS PLACEBO	-5.99	0.0021	-0.50
													BREX+SERT VS SERT	-5.08	0.0106	-0.42
													BREX+SERT VS BREX	-4.24	0.0384	-0.35
													BREX VS PLACEBO	-1.74	0.3868	-0.14
													SERT VS PLACEBO	-0.91	0.6399	-0.08

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, (POOLED) STUDY CENTER, TYPE OF TRAUMA, VISIT, TREATMENT BY VISIT AND BASELINE BY

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STAT-1.2
 Adjusted Mean Change from Baseline (Day 0) in SOTS Line Items at Week 12 - MMRM
 (Intent to Treat Sample)

SOTS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹		P-VALUE ¹		
SOTS-RE-EXPERIE NCING	74	4.64	-2.34	67	4.61	-1.71	70	4.63	-1.93	75	4.44	-1.84	BREX+SERT VS PLACEBO	-0.50	0.0743	-0.29
													BREX+SERT VS SERT	-0.41	0.1485	-0.24
													BREX+SERT VS BREX	-0.63	0.0344	-0.36
													BREX VS PLACEBO	0.13	0.6549	0.08
													SERT VS PLACEBO	-0.09	0.7513	-0.05
SOTS-HYPERAROUS AL	74	4.53	-1.15	67	4.45	-1.08	70	4.59	-1.65	75	4.48	-1.04	BREX+SERT VS PLACEBO	-0.11	0.6565	-0.07
													BREX+SERT VS SERT	0.50	0.0601	0.32
													BREX+SERT VS BREX	-0.07	0.7903	-0.04
													BREX VS PLACEBO	-0.04	0.8779	-0.03
													SERT VS PLACEBO	-0.61	0.0196	-0.39
SOTS-AFFECTIVE DYSREGULATION	74	3.46	-1.58	67	3.79	-1.49	70	3.81	-1.82	75	3.45	-1.50	BREX+SERT VS PLACEBO	-0.08	0.7494	-0.05
													BREX+SERT VS SERT	0.24	0.3563	0.15
													BREX+SERT VS BREX	-0.09	0.7310	-0.06
													BREX VS PLACEBO	0.01	0.9641	0.01
													SERT VS PLACEBO	-0.32	0.2122	-0.21
SOTS-IMPULSIVIT Y	74	1.95	-0.48	67	1.69	-0.53	70	2.04	-0.60	75	2.03	-0.59	BREX+SERT VS PLACEBO	0.11	0.4865	0.11

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STAT-1.2
 Adjusted Mean Change from Baseline (Day 0) in SOTS Line Items at Week 12 - MMRM
 (Intent to Treat Sample)

SOTS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹		P-VALUE ¹		
SOTS-IMPULSIVITY													BREX+SERT VS SERT	0.13	0.4422	0.13
													BREX+SERT VS BREX	0.05	0.7742	0.05
													BREX VS PLACEBO	0.06	0.7127	0.06
													SERT VS PLACEBO	-0.01	0.9318	-0.01
SOTS-AVOIDANCE	74	4.84	-1.75	67	4.63	-1.31	70	4.89	-1.48	75	4.71	-1.47	BREX+SERT VS PLACEBO	-0.27	0.3319	-0.16
													BREX+SERT VS SERT	-0.27	0.3435	-0.16
													BREX+SERT VS BREX	-0.44	0.1441	-0.25
													BREX VS PLACEBO	0.16	0.5762	0.09
													SERT VS PLACEBO	-0.00	0.9956	-0.00
SOTS-NUMBING	74	3.01	-1.07	67	2.93	-0.71	70	3.00	-0.90	75	3.19	-0.97	BREX+SERT VS PLACEBO	-0.10	0.6892	-0.07
													BREX+SERT VS SERT	-0.18	0.4808	-0.12
													BREX+SERT VS BREX	-0.37	0.1658	-0.23
													BREX VS PLACEBO	0.27	0.3069	0.17
													SERT VS PLACEBO	0.08	0.7529	0.05
SOTS-ATTENTIVE CONSCIOUSNESS DISSOCIATION	74	2.08	-0.75	67	2.27	-0.68	70	1.70	-0.55	75	2.01	-0.40	BREX+SERT VS PLACEBO	-0.35	0.0455	-0.33
													BREX+SERT VS SERT	-0.19	0.2806	-0.18
													BREX+SERT VS BREX	-0.06	0.7318	-0.06

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, (POOLED) STUDY CENTER, TYPE OF TRAUMA, VISIT, TREATMENT BY VISIT AND BASELINE BY

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BREXPIRAZOLE
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STAT-1.2
 Adjusted Mean Change from Baseline (Day 0) in SOTS Line Items at Week 12 - MMRM
 (Intent to Treat Sample)

SOTS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹		P-VALUE ¹		
SOTS-ATTENTIN CONSCIOUSNESS DISSOCIATION													BREX VS PLACEBO	-0.29	0.1203	-0.26
													SERT VS PLACEBO	-0.16	0.3679	-0.15
SOTS-SELF PERCEPTION	74	3.93	-1.69	67	4.01	-1.51	70	4.04	-1.49	75	3.91	-1.63	BREX+SERT VS PLACEBO	-0.06	0.8272	-0.04
													BREX+SERT VS SERT	-0.20	0.4447	-0.13
													BREX+SERT VS BREX	-0.17	0.5223	-0.11
													BREX VS PLACEBO	0.12	0.6604	0.07
													SERT VS PLACEBO	0.14	0.5779	0.09
SOTS-INTERPERSO NAL RELATION	74	4.66	-1.62	67	4.54	-1.49	70	4.61	-1.77	75	4.64	-1.22	BREX+SERT VS PLACEBO	-0.40	0.1589	-0.23
													BREX+SERT VS SERT	0.15	0.6021	0.09
													BREX+SERT VS BREX	-0.13	0.6682	-0.07
													BREX VS PLACEBO	-0.27	0.3647	-0.15
													SERT VS PLACEBO	-0.55	0.0547	-0.32
SOTS-ALTERATION S IN SEXUAL RELATIONS	74	2.88	-1.05	67	2.97	-0.91	70	2.91	-0.74	75	2.39	-1.04	BREX+SERT VS PLACEBO	-0.01	0.9734	-0.01
													BREX+SERT VS SERT	-0.30	0.2684	-0.19

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STAT-1.2
 Adjusted Mean Change from Baeline (Day 0) in SOTS Line Items at Week 12 - MMRM
 (Intent to Treat Sample)

SOTS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹		P-VALUE ¹		
SOTS-ALTERATION S IN SEXUAL RELATIONS													BREX+SERT VS BREX	-0.14	0.6242	-0.08
													BREX VS PLACEBO	0.13	0.6425	0.08
													SERT VS PLACEBO	0.29	0.2805	0.18
SOTS-SUSTAINING BELIEFS	74	2.82	-1.12	67	2.48	-0.80	70	2.47	-0.70	75	2.69	-0.78	BREX+SERT VS PLACEBO	-0.34	0.1243	-0.25
													BREX+SERT VS SERT	-0.43	0.0599	-0.32
													BREX+SERT VS BREX	-0.33	0.1657	-0.23
													BREX VS PLACEBO	-0.01	0.9546	-0.01
													SERT VS PLACEBO	0.09	0.7017	0.06
SOTS-SOMATIC DYSREGULATION	74	2.03	-0.60	67	1.81	-0.60	70	1.86	-0.52	75	1.71	-0.31	BREX+SERT VS PLACEBO	-0.29	0.0980	-0.27
													BREX+SERT VS SERT	-0.08	0.6656	-0.07
													BREX+SERT VS BREX	-0.00	0.9965	-0.00
													BREX VS PLACEBO	-0.29	0.1169	-0.26
													SERT VS PLACEBO	-0.21	0.2265	-0.20
SOTS TOTAL SCORE	74	40.82	-15.2	67	40.16	-12.7	70	40.56	-14.0	75	39.64	-12.8	BREX+SERT VS PLACEBO	-2.36	0.1481	-0.24
													BREX+SERT VS SERT	-1.15	0.4872	-0.12

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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STAT-1.2
 Adjusted Mean Change from Baseline (Day 0) in SOTS Line Items at Week 12 - MMRM
 (Intent to Treat Sample)

SOTS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹		P-VALUE ¹		
SOTS TOTAL SCORE													BREX+SERT VS BREX	-2.46	0.1561	-0.24
													BREX VS PLACEBO	0.10	0.9554	0.01
													SERT VS PLACEBO	-1.21	0.4624	-0.12

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, (POOLED) STUDY CENTER, TYPE OF TRAUMA, VISIT, TREATMENT BY VISIT AND BASELINE BY

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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Adjusted Mean Change [REDACTED] STAT-1.3 in PCL-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

PCL5 Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN's D EFFECT SIZE
	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹				
PCL5-REP DISTRB UNWNTD MEMRS STRESS EXP	77	2.38	-1.16	69	2.26	-0.85	75	2.60	-0.85	78	2.21	-0.85	BREX+SERT VS PLACEBO	-0.31	0.0715	-0.29
													BREX+SERT VS SERT	-0.32	0.0749	-0.29
													BREX+SERT VS BREX	-0.31	0.0923	-0.28
													BREX VS PLACEBO	-0.00	0.9831	-0.00
													SERT VS PLACEBO	0.00	0.9845	0.00
PCL5-REP DISTRB DREAMS STRESS EXP	77	1.82	-0.89	69	2.12	-0.71	75	2.21	-0.69	78	1.82	-0.67	BREX+SERT VS PLACEBO	-0.22	0.2417	-0.19
													BREX+SERT VS SERT	-0.20	0.2835	-0.17
													BREX+SERT VS BREX	-0.18	0.3588	-0.15
													BREX VS PLACEBO	-0.04	0.8524	-0.03
													SERT VS PLACEBO	-0.01	0.9445	-0.01
PCL5-SUDDN FEELNG STRES EXP HAPPN AGAIN	77	1.55	-0.74	69	1.71	-0.69	75	1.61	-0.59	78	1.44	-0.84	BREX+SERT VS PLACEBO	0.10	0.5486	0.10
													BREX+SERT VS SERT	-0.15	0.3909	-0.14
													BREX+SERT VS BREX	-0.04	0.8125	-0.04
													BREX VS PLACEBO	0.15	0.4174	0.13

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Adjusted Mean Change [REDACTED] STAT-1.3 in PCL-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

PCL5 Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
PCL5-SUDDN FEELNG STRES EXP HAPPN AGAIN													SERT VS PLACEBO	0.25	0.1434	0.24
PCL5-FEEL UPST SMTHNG REMNDS STRESS EXP	77	2.66	-1.11	69	2.39	-0.67	75	2.52	-0.70	78	2.38	-0.68	BREX+SERT VS PLACEBO	-0.44	0.0214	-0.37
													BREX+SERT VS SERT	-0.41	0.0331	-0.35
													BREX+SERT VS BREX	-0.44	0.0269	-0.37
													BREX VS PLACEBO	0.01	0.9676	0.01
													SERT VS PLACEBO	-0.03	0.8914	-0.02
PCL5-HAVNG STRNG PHY REACTNS STRESS EXP	77	2.39	-1.06	69	2.20	-0.83	75	2.41	-0.66	78	2.26	-0.74	BREX+SERT VS PLACEBO	-0.32	0.0996	-0.27
													BREX+SERT VS SERT	-0.40	0.0409	-0.33
													BREX+SERT VS BREX	-0.24	0.2473	-0.19
													BREX VS PLACEBO	-0.08	0.6847	-0.07
													SERT VS PLACEBO	0.08	0.6614	0.07

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, (POOLED) STUDY CENTER, TYPE OF TRAUMA, VISIT, TREATMENT BY VISIT AND BASELINE BY

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 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIPIRAZOLE STAT-1.3 FINAL

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Adjusted Mean Change [REDACTED] STAT-1.3 in PCL-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

PCL5 Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
PCL5-AVOID MEMRS THOUGHTS FEEL STRES EXP	77	2.64	-1.07	69	2.46	-0.61	75	2.57	-0.52	78	2.63	-0.63	BREX+SERT VS PLACEBO	-0.44	0.0395	-0.33
													BREX+SERT VS SERT	-0.56	0.0116	-0.41
													BREX+SERT VS BREX	-0.47	0.0399	-0.34
													BREX VS PLACEBO	0.03	0.9077	0.02
													SERT VS PLACEBO	0.11	0.6017	0.08
PCL5-AVOID EXTRNL REMINDRS STRESS EXP	77	2.56	-0.91	69	2.62	-0.82	75	2.75	-0.69	78	2.44	-0.61	BREX+SERT VS PLACEBO	-0.30	0.1626	-0.23
													BREX+SERT VS SERT	-0.22	0.3205	-0.16
													BREX+SERT VS BREX	-0.09	0.6967	-0.06
													BREX VS PLACEBO	-0.21	0.3466	-0.16
													SERT VS PLACEBO	-0.08	0.7043	-0.06
PCL5-TROUBLE REMBRNG IMP PRTS STRES EXP	77	1.26	-0.71	69	1.45	-0.40	75	1.21	-0.62	78	1.23	-0.31	BREX+SERT VS PLACEBO	-0.40	0.0133	-0.40
													BREX+SERT VS SERT	-0.09	0.6039	-0.08
													BREX+SERT VS BREX	-0.31	0.0704	-0.30
													BREX VS PLACEBO	-0.09	0.5896	-0.09

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, (POOLED) STUDY CENTER, TYPE OF TRAUMA, VISIT, TREATMENT BY VISIT AND BASELINE BY

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Adjusted Mean Change [REDACTED] STAT-1.3 in PCL-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

PCL5 Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
PCL5-TROUBLE REMBRNG IMP PRTS STRES EXP													SERT VS PLACEBO	-0.32	0.0520	-0.32
PCL5-HAVG STRNG NEG BELFS SELF PPL WRLD	77	2.29	-1.23	69	2.14	-0.74	75	2.20	-0.84	78	2.13	-0.55	BREX+SERT VS PLACEBO	-0.68	0.0003	-0.59
													BREX+SERT VS SERT	-0.39	0.0407	-0.33
													BREX+SERT VS BREX	-0.49	0.0140	-0.41
													BREX VS PLACEBO	-0.20	0.3099	-0.17
													SERT VS PLACEBO	-0.29	0.1146	-0.26
PCL5-BLAMNG SELF OTHRS FOR STRESSFL EXP	77	2.13	-0.87	69	2.22	-0.79	75	2.24	-0.86	78	2.13	-0.68	BREX+SERT VS PLACEBO	-0.19	0.3678	-0.14
													BREX+SERT VS SERT	-0.01	0.9523	-0.01
													BREX+SERT VS BREX	-0.08	0.7148	-0.06
													BREX VS PLACEBO	-0.11	0.6233	-0.08
													SERT VS PLACEBO	-0.18	0.4037	-0.14

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, (POOLED) STUDY CENTER, TYPE OF TRAUMA, VISIT, TREATMENT BY VISIT AND BASELINE BY

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Adjusted Mean Change [REDACTED] STAT-1.3 in PCL-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

PCL5 Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
PCL5-HAVNG STRNG NEG FEELNGS	77	2.44	-1.05	69	2.51	-0.74	75	2.49	-0.90	78	2.32	-0.74	BREX+SERT VS PLACEBO	-0.31	0.1131	-0.26
													BREX+SERT VS SERT	-0.15	0.4469	-0.12
													BREX+SERT VS BREX	-0.32	0.1280	-0.25
													BREX VS PLACEBO	0.01	0.9775	0.00
													SERT VS PLACEBO	-0.16	0.4192	-0.13
PCL5-LOSS INTRST ACTIVITIES USD TO ENJOY	77	2.61	-1.34	69	2.38	-0.78	75	2.41	-0.66	78	2.33	-0.76	BREX+SERT VS PLACEBO	-0.57	0.0041	-0.47
													BREX+SERT VS SERT	-0.68	0.0009	-0.55
													BREX+SERT VS BREX	-0.56	0.0079	-0.44
													BREX VS PLACEBO	-0.01	0.9433	-0.01
													SERT VS PLACEBO	0.10	0.5991	0.09
PCL5-FEELNG DISTANT CUT OFF FROM OTHERS	77	2.53	-1.12	69	2.68	-0.88	75	2.75	-0.84	78	2.50	-0.62	BREX+SERT VS PLACEBO	-0.50	0.0107	-0.41
													BREX+SERT VS SERT	-0.28	0.1647	-0.23
													BREX+SERT VS BREX	-0.24	0.2412	-0.19
													BREX VS PLACEBO	-0.26	0.2050	-0.21

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, (POOLED) STUDY CENTER, TYPE OF TRAUMA, VISIT, TREATMENT BY VISIT AND BASELINE BY

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Adjusted Mean Change [REDACTED] in PCL-5 Line Items [REDACTED] 10 - MMRM
 (Intent to Treat Sample)

PCL5 Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN'S D EFFECT SIZE
	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹		P-VALUE ¹		
PCL5-FEELNG DISTANT CUT OFF FROM OTHERS													SERT VS PLACEBO	-0.22	0.2564	-0.18
PCL5-TRBLE EXPERINCNG POSITIVE FEELNGS	77	2.05	-0.88	69	2.19	-0.65	75	2.16	-0.66	78	2.00	-0.71	BREX+SERT VS PLACEBO	-0.16	0.3492	-0.15
													BREX+SERT VS SERT	-0.22	0.2231	-0.20
													BREX+SERT VS BREX	-0.23	0.2235	-0.20
													BREX VS PLACEBO	0.06	0.7334	0.06
													SERT VS PLACEBO	0.05	0.7582	0.05
PCL5-IRRITBLE BEHAV ANGRY OUTBRST AGRSV	77	1.96	-0.79	69	1.84	-0.58	75	1.83	-0.63	78	1.82	-0.58	BREX+SERT VS PLACEBO	-0.21	0.2766	-0.18
													BREX+SERT VS SERT	-0.16	0.4060	-0.14
													BREX+SERT VS BREX	-0.21	0.3047	-0.17
													BREX VS PLACEBO	-0.00	0.9982	-0.00
													SERT VS PLACEBO	-0.05	0.8090	-0.04

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Adjusted Mean Change [REDACTED] STAT-1.3 in PCL-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

PCL5 Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
PCL5-TAKNG TOO MNY RISKS THT CAUSE HARM	77	0.78	-0.30	69	0.71	-0.18	75	0.79	-0.48	78	0.72	-0.21	BREX+SERT VS PLACEBO	-0.09	0.4502	-0.12
													BREX+SERT VS SERT	0.18	0.1340	0.24
													BREX+SERT VS BREX	-0.12	0.3379	-0.16
													BREX VS PLACEBO	0.03	0.8022	0.04
													SERT VS PLACEBO	-0.27	0.0237	-0.37
PCL5-BEING SUPERALERT WATCHFUL ON GUARD	77	2.86	-0.70	69	2.78	-0.62	75	2.69	-0.63	78	2.68	-0.64	BREX+SERT VS PLACEBO	-0.07	0.7349	-0.05
													BREX+SERT VS SERT	-0.07	0.7235	-0.06
													BREX+SERT VS BREX	-0.08	0.6897	-0.07
													BREX VS PLACEBO	0.02	0.9365	0.01
													SERT VS PLACEBO	0.00	0.9823	0.00
PCL5-FEELING JUMPY OR EASILY STARTLED	77	2.26	-0.84	69	2.23	-0.73	75	1.97	-0.58	78	2.24	-0.83	BREX+SERT VS PLACEBO	-0.00	0.9802	-0.00
													BREX+SERT VS SERT	-0.25	0.1856	-0.22
													BREX+SERT VS BREX	-0.11	0.5805	-0.09
													BREX VS PLACEBO	0.10	0.5919	0.09

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Adjusted Mean Change [REDACTED] in PCL-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

PCL5 Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN'S D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹				
PCL5-FEELING JUMPY OR EASILY STARTLED													SERT VS PLACEBO	0.25	0.1874	0.21
PCL5-HAVNG DIFFICULTY CONCENTRATNG	77	2.58	-0.94	69	2.57	-0.75	75	2.35	-0.69	78	2.38	-0.62	BREX+SERT VS PLACEBO	-0.32	0.0747	-0.29
													BREX+SERT VS SERT	-0.25	0.1674	-0.22
													BREX+SERT VS BREX	-0.20	0.2991	-0.17
													BREX VS PLACEBO	-0.12	0.5099	-0.11
													SERT VS PLACEBO	-0.07	0.7080	-0.06
PCL5-TROUBLE FALLING OR STAYING ASLEEP	77	2.47	-0.94	69	2.74	-0.90	75	2.81	-0.53	78	2.83	-0.70	BREX+SERT VS PLACEBO	-0.24	0.2503	-0.19
													BREX+SERT VS SERT	-0.41	0.0509	-0.32
													BREX+SERT VS BREX	-0.03	0.8788	-0.03
													BREX VS PLACEBO	-0.20	0.3415	-0.16
													SERT VS PLACEBO	0.17	0.4001	0.14
PCL-5 TOTAL SCORE	77	44.21	-18.6	69	44.20	-13.8	75	44.59	-13.7	78	42.49	-12.6	BREX+SERT VS PLACEBO	-6.01	0.0143	-0.40
													BREX+SERT VS SERT	-4.93	0.0487	-0.32

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STAT-1.3
 Adjusted Mean Change [REDACTED] in PCL-5 Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

PCL5 Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹		P-VALUE ¹		
PCL-5 TOTAL SCORE													BREX+SERT VS BREX	-4.84	0.0607	-0.31
													BREX VS PLACEBO	-1.18	0.6433	-0.08
													SERT VS PLACEBO	-1.08	0.6586	-0.07

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BREXPIRAZOLE
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STAT-1.4
Adjusted Mean Change [REDACTED] in HADS Line Items [REDACTED] - MMRM
(Intent to Treat Sample)

HADS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN'S D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹				
HADS01-I FEEL TENSE OR WOUND UP	77	1.97	-0.73	68	1.79	-0.23	75	1.92	-0.40	78	1.91	-0.42	BREX+SERT VS PLACEBO	-0.31	0.0394	-0.33
													BREX+SERT VS SERT	-0.33	0.0305	-0.35
													BREX+SERT VS BREX	-0.50	0.0019	-0.52
													BREX VS PLACEBO	0.19	0.2233	0.20
													SERT VS PLACEBO	0.02	0.8822	0.02
HADS01-ENJOY THE THINGS I USED TO ENJOY	77	1.74	-0.56	68	1.59	-0.51	75	1.63	-0.23	78	1.55	-0.54	BREX+SERT VS PLACEBO	-0.02	0.8919	-0.02
													BREX+SERT VS SERT	-0.33	0.0386	-0.34
													BREX+SERT VS BREX	-0.05	0.7712	-0.05
													BREX VS PLACEBO	0.03	0.8685	0.03
													SERT VS PLACEBO	0.31	0.0494	0.32
HADS01-SOMETHIN G AWFUL ABOUT TO HAPPEN	77	1.94	-0.72	68	1.79	-0.38	75	1.88	-0.39	78	1.94	-0.58	BREX+SERT VS PLACEBO	-0.13	0.3534	-0.15
													BREX+SERT VS SERT	-0.33	0.0284	-0.36
													BREX+SERT VS BREX	-0.33	0.0323	-0.36
													BREX VS PLACEBO	0.20	0.1959	0.22
													SERT VS PLACEBO	0.19	0.1909	0.21

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Adjusted Mean Change [REDACTED] STAT-1.4 in HADS Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

HADS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
HADS01-I CAN LAUGH AND SEE FUNNY SIDE	77	1.08	-0.38	68	1.06	-0.03	75	1.01	-0.13	78	0.92	-0.23	BREX+SERT VS PLACEBO	-0.15	0.2374	-0.19
													BREX+SERT VS SERT	-0.25	0.0541	-0.31
													BREX+SERT VS BREX	-0.35	0.0085	-0.44
													BREX VS PLACEBO	0.21	0.1205	0.26
													SERT VS PLACEBO	0.10	0.4355	0.13
HADS01-WORRYING THOUGHTS GO THROUGH MIND	77	2.06	-0.71	68	1.94	-0.33	75	2.07	-0.42	78	2.12	-0.43	BREX+SERT VS PLACEBO	-0.29	0.0646	-0.30
													BREX+SERT VS SERT	-0.29	0.0677	-0.30
													BREX+SERT VS BREX	-0.38	0.0227	-0.38
													BREX VS PLACEBO	0.09	0.5773	0.09
													SERT VS PLACEBO	0.00	0.9893	0.00
HADS01-I FEEL CHEERFUL	77	1.47	-0.56	68	1.32	-0.32	75	1.41	-0.37	78	1.24	-0.31	BREX+SERT VS PLACEBO	-0.25	0.0526	-0.31
													BREX+SERT VS SERT	-0.19	0.1371	-0.24
													BREX+SERT VS BREX	-0.24	0.0835	-0.29
													BREX VS PLACEBO	-0.01	0.9180	-0.02
													SERT VS PLACEBO	-0.06	0.6638	-0.07

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Adjusted Mean Change [REDACTED] STAT-1.4 in HADS Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

HADS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN'S D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
HADS01-SIT AT EASE AND FEEL RELAXED	77	1.79	-0.49	68	1.72	-0.23	75	1.73	-0.23	78	1.76	-0.35	BREX+SERT VS PLACEBO	-0.14	0.2632	-0.18
													BREX+SERT VS SERT	-0.26	0.0400	-0.34
													BREX+SERT VS BREX	-0.26	0.0476	-0.33
													BREX VS PLACEBO	0.12	0.3449	0.16
													SERT VS PLACEBO	0.12	0.3290	0.16
HADS01-I FEEL AS IF I AM SLOWED DOWN	77	1.60	-0.65	68	1.43	-0.37	75	1.40	-0.39	78	1.51	-0.54	BREX+SERT VS PLACEBO	-0.10	0.4793	-0.11
													BREX+SERT VS SERT	-0.26	0.0805	-0.28
													BREX+SERT VS BREX	-0.28	0.0696	-0.30
													BREX VS PLACEBO	0.18	0.2403	0.20
													SERT VS PLACEBO	0.16	0.2794	0.18
HADS01-BUTTERFL IES IN THE STOMACH	77	1.31	-0.36	68	1.29	-0.19	75	1.41	-0.38	78	1.32	-0.45	BREX+SERT VS PLACEBO	0.08	0.5221	0.10
													BREX+SERT VS SERT	0.02	0.9061	0.02
													BREX+SERT VS BREX	-0.18	0.2075	-0.21
													BREX VS PLACEBO	0.26	0.0603	0.31
													SERT VS PLACEBO	0.07	0.6053	0.08

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, (POOLED) STUDY CENTER, TYPE OF TRAUMA, VISIT, TREATMENT BY VISIT AND BASELINE BY

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Adjusted Mean Change [REDACTED] STAT-1.4 in HADS Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

HADS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹				
HADS01-LOST INTEREST IN MY APPEARANCE	77	1.35	-0.42	68	1.28	-0.31	75	1.40	-0.16	78	1.42	-0.26	BREX+SERT VS PLACEBO	-0.16	0.2080	-0.20
													BREX+SERT VS SERT	-0.26	0.0491	-0.32
													BREX+SERT VS BREX	-0.11	0.4299	-0.13
													BREX VS PLACEBO	-0.05	0.6901	-0.07
													SERT VS PLACEBO	0.10	0.4551	0.12
HADS01-FEEL RESTLESS BE ON THE MOVE	77	1.90	-0.59	68	1.75	-0.20	75	1.85	-0.36	78	1.85	-0.36	BREX+SERT VS PLACEBO	-0.23	0.1186	-0.25
													BREX+SERT VS SERT	-0.23	0.1153	-0.26
													BREX+SERT VS BREX	-0.39	0.0113	-0.42
													BREX VS PLACEBO	0.17	0.2731	0.18
													SERT VS PLACEBO	0.01	0.9652	0.01
HADS01-LOOK FORWARD WITH ENJOYMENT	77	1.60	-0.51	68	1.53	-0.17	75	1.59	-0.26	78	1.29	-0.30	BREX+SERT VS PLACEBO	-0.21	0.1853	-0.21
													BREX+SERT VS SERT	-0.25	0.1197	-0.25
													BREX+SERT VS BREX	-0.34	0.0415	-0.34
													BREX VS PLACEBO	0.13	0.4292	0.13
													SERT VS PLACEBO	0.04	0.8053	0.04

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, (POOLED) STUDY CENTER, TYPE OF TRAUMA, VISIT, TREATMENT BY VISIT AND BASELINE BY

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BREXPIRAZOLE
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Adjusted Mean Change [REDACTED] STAT-1.4 in HADS Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

HADS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN'S D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹				
HADS01-I GET SUDDEN FEELINGS OF PANIC	77	1.61	-0.43	68	1.68	-0.27	75	1.71	-0.37	78	1.60	-0.34	BREX+SERT VS PLACEBO	-0.09	0.4975	-0.11
													BREX+SERT VS SERT	-0.05	0.7002	-0.06
													BREX+SERT VS BREX	-0.16	0.2751	-0.18
													BREX VS PLACEBO	0.06	0.6444	0.08
													SERT VS PLACEBO	-0.04	0.7765	-0.05
HADS01-ENJOY GOOD BOOK	77	1.44	-0.45	68	1.18	-0.12	75	1.12	-0.25	78	1.03	-0.25	BREX+SERT VS PLACEBO	-0.20	0.1530	-0.23
													BREX+SERT VS SERT	-0.20	0.1558	-0.23
													BREX+SERT VS BREX	-0.33	0.0232	-0.38
													BREX VS PLACEBO	0.13	0.3444	0.16
													SERT VS PLACEBO	0.00	0.9935	0.00
HADS SUBSCALE A TOTAL SCORE	77	12.58	-4.00	68	11.97	-1.60	75	12.57	-2.46	78	12.49	-2.80	BREX+SERT VS PLACEBO	-1.20	0.0793	-0.28
													BREX+SERT VS SERT	-1.55	0.0274	-0.36
													BREX+SERT VS BREX	-2.41	0.0010	-0.55
													BREX VS PLACEBO	1.20	0.0930	0.28
													SERT VS PLACEBO	0.34	0.6172	0.08

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, (POOLED) STUDY CENTER, TYPE OF TRAUMA, VISIT, TREATMENT BY VISIT AND BASELINE BY

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Adjusted Mean Change [REDACTED] STAT-1.4 in HADS Line Items [REDACTED] - MMRM
 (Intent to Treat Sample)

HADS Line Items	BREX+SERT ²			BREX ²			SERT ²			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
HADS SUBSCALE	77	10.27	-3.66	68	9.38	-1.75	75	9.56	-1.72	78	8.97	-2.21	BREX+SERT VS PLACEBO	-1.45	0.0249	-0.36
D TOTAL SCORE													BREX+SERT VS SERT	-1.94	0.0033	-0.48
													BREX+SERT VS BREX	-1.91	0.0053	-0.47
													BREX VS PLACEBO	0.46	0.4939	0.11
													SERT VS PLACEBO	0.49	0.4476	0.12

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, (POOLED) STUDY CENTER, TYPE OF TRAUMA, VISIT, TREATMENT BY VISIT AND BASELINE BY

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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
AVISITN	4	3 6 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	
COMBFL	2	N Y

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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction
(Intent to Treat Sample)

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The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	299	

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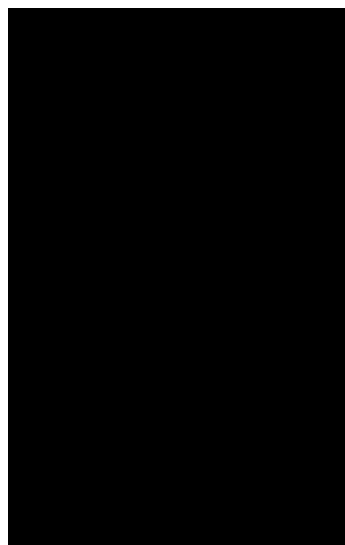
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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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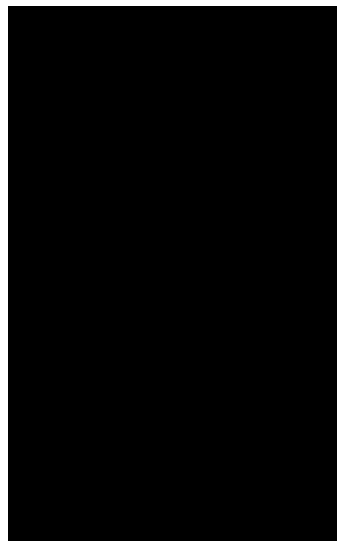
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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction
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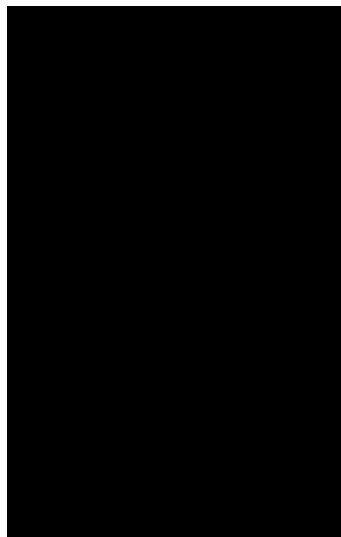
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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction
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The Mixed Procedure



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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

SEX 2 F M

Dimensions

Covariance Parameters	10
Columns in X	91
Columns in Z	0
Subjects	299
Max Obs per Subject	4

Number of Observations

Number of Observations Read	996
Number of Observations Used	996
Number of Observations Not Used	0

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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	7347.61199056	
1	2	6870.77895648	0.00048752
2	1	6869.39176021	0.00001813
3	1	6869.34408788	0.00000003
4	1	6869.34400894	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	78.3536
UN(2,1)	SUBJID	52.5580
UN(2,2)	SUBJID	113.32
UN(3,1)	SUBJID	43.5675
UN(3,2)	SUBJID	89.6909
UN(3,3)	SUBJID	124.09
UN(4,1)	SUBJID	48.7794

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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,2)	SUBJID	90.3794
UN(4,3)	SUBJID	106.13
UN(4,4)	SUBJID	148.60

Fit Statistics

-2 Res Log Likelihood	6869.3
AIC (Smaller is Better)	6889.3
AICC (Smaller is Better)	6889.6
BIC (Smaller is Better)	6926.3

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
9	478.27	<.0001

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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
POOLCNTR	9	278	1.66	0.0986
COMBFL	1	278	3.11	0.0788
AVISITN	3	226	0.79	0.5023
TRTPN	3	264	2.42	0.0665
AVISITN*TRTPN	9	357	1.58	0.1209
SEX	1	287	0.04	0.8490
AVISITN*SEX	3	232	1.80	0.1474
TRTPN*SEX	3	264	0.35	0.7878
AVISITN*TRTPN*SEX	9	357	0.96	0.4707
BASE*AVISITN	4	239	14.93	<.0001

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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
SEX			F			
SEX			M			
AVISITN*SEX			F	3		
AVISITN*SEX			M	3		
AVISITN*SEX			F	6		
AVISITN*SEX			M	6		
AVISITN*SEX			F	10		
AVISITN*SEX			M	10		
AVISITN*SEX			F	12		
AVISITN*SEX			M	12		
TRTPN*SEX			F		1	1
TRTPN*SEX			M		1	-1
TRTPN*SEX			F		2	
TRTPN*SEX			M		2	
TRTPN*SEX			F		3	
TRTPN*SEX			M		3	
TRTPN*SEX			F		900	-1

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*SEX			M		900	1
AVISITN*TRTPN*SEX			F	3	1	
AVISITN*TRTPN*SEX			M	3	1	
AVISITN*TRTPN*SEX			F	3	2	
AVISITN*TRTPN*SEX			M	3	2	
AVISITN*TRTPN*SEX			F	3	3	
AVISITN*TRTPN*SEX			M	3	3	
AVISITN*TRTPN*SEX			F	3	900	
AVISITN*TRTPN*SEX			M	3	900	
AVISITN*TRTPN*SEX			F	6	1	
AVISITN*TRTPN*SEX			M	6	1	
AVISITN*TRTPN*SEX			F	6	2	
AVISITN*TRTPN*SEX			M	6	2	
AVISITN*TRTPN*SEX			F	6	3	
AVISITN*TRTPN*SEX			M	6	3	
AVISITN*TRTPN*SEX			F	6	900	
AVISITN*TRTPN*SEX			M	6	900	
AVISITN*TRTPN*SEX			F	10	1	1

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY SEX AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*SEX			M	10	1	-1
AVISITN*TRTPN*SEX			F	10	2	
AVISITN*TRTPN*SEX			M	10	2	
AVISITN*TRTPN*SEX			F	10	3	
AVISITN*TRTPN*SEX			M	10	3	
AVISITN*TRTPN*SEX			F	10	900	-1
AVISITN*TRTPN*SEX			M	10	900	1
AVISITN*TRTPN*SEX			F	12	1	
AVISITN*TRTPN*SEX			M	12	1	
AVISITN*TRTPN*SEX			F	12	2	
AVISITN*TRTPN*SEX			M	12	2	
AVISITN*TRTPN*SEX			F	12	3	
AVISITN*TRTPN*SEX			M	12	3	
AVISITN*TRTPN*SEX			F	12	900	
AVISITN*TRTPN*SEX			M	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY SEX AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Coefficients for Dummy W vs. Dummy Y BY SEX AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						

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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
SEX			F			
SEX			M			
AVISITN*SEX			F	3		
AVISITN*SEX			M	3		
AVISITN*SEX			F	6		
AVISITN*SEX			M	6		
AVISITN*SEX			F	10		

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*SEX			M	10		
AVISITN*SEX			F	12		
AVISITN*SEX			M	12		
TRTPN*SEX			F		1	1
TRTPN*SEX			M		1	-1
TRTPN*SEX			F		2	
TRTPN*SEX			M		2	
TRTPN*SEX			F		3	-1
TRTPN*SEX			M		3	1
TRTPN*SEX			F		900	
TRTPN*SEX			M		900	
AVISITN*TRTPN*SEX			F	3	1	
AVISITN*TRTPN*SEX			M	3	1	
AVISITN*TRTPN*SEX			F	3	2	
AVISITN*TRTPN*SEX			M	3	2	
AVISITN*TRTPN*SEX			F	3	3	
AVISITN*TRTPN*SEX			M	3	3	
AVISITN*TRTPN*SEX			F	3	900	

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*SEX			M	3	900	
AVISITN*TRTPN*SEX			F	6	1	
AVISITN*TRTPN*SEX			M	6	1	
AVISITN*TRTPN*SEX			F	6	2	
AVISITN*TRTPN*SEX			M	6	2	
AVISITN*TRTPN*SEX			F	6	3	
AVISITN*TRTPN*SEX			M	6	3	
AVISITN*TRTPN*SEX			F	6	900	
AVISITN*TRTPN*SEX			M	6	900	
AVISITN*TRTPN*SEX			F	10	1	1
AVISITN*TRTPN*SEX			M	10	1	-1
AVISITN*TRTPN*SEX			F	10	2	
AVISITN*TRTPN*SEX			M	10	2	
AVISITN*TRTPN*SEX			F	10	3	-1
AVISITN*TRTPN*SEX			M	10	3	1
AVISITN*TRTPN*SEX			F	10	900	
AVISITN*TRTPN*SEX			M	10	900	
AVISITN*TRTPN*SEX			F	12	1	

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*SEX			M	12	1	
AVISITN*TRTPN*SEX			F	12	2	
AVISITN*TRTPN*SEX			M	12	2	
AVISITN*TRTPN*SEX			F	12	3	
AVISITN*TRTPN*SEX			M	12	3	
AVISITN*TRTPN*SEX			F	12	900	
AVISITN*TRTPN*SEX			M	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
SEX			F			
SEX			M			
AVISITN*SEX			F	3		
AVISITN*SEX			M	3		
AVISITN*SEX			F	6		
AVISITN*SEX			M	6		
AVISITN*SEX			F	10		
AVISITN*SEX			M	10		
AVISITN*SEX			F	12		
AVISITN*SEX			M	12		
TRTPN*SEX			F		1	1
TRTPN*SEX			M		1	-1
TRTPN*SEX			F		2	-1
TRTPN*SEX			M		2	1
TRTPN*SEX			F		3	
TRTPN*SEX			M		3	
TRTPN*SEX			F		900	

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*SEX			M		900	
AVISITN*TRTPN*SEX			F	3	1	
AVISITN*TRTPN*SEX			M	3	1	
AVISITN*TRTPN*SEX			F	3	2	
AVISITN*TRTPN*SEX			M	3	2	
AVISITN*TRTPN*SEX			F	3	3	
AVISITN*TRTPN*SEX			M	3	3	
AVISITN*TRTPN*SEX			F	3	900	
AVISITN*TRTPN*SEX			M	3	900	
AVISITN*TRTPN*SEX			F	6	1	
AVISITN*TRTPN*SEX			M	6	1	
AVISITN*TRTPN*SEX			F	6	2	
AVISITN*TRTPN*SEX			M	6	2	
AVISITN*TRTPN*SEX			F	6	3	
AVISITN*TRTPN*SEX			M	6	3	
AVISITN*TRTPN*SEX			F	6	900	
AVISITN*TRTPN*SEX			M	6	900	
AVISITN*TRTPN*SEX			F	10	1	1

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY SEX AT Phase B Week 10

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*SEX			M	10	1	-1
AVISITN*TRTPN*SEX			F	10	2	-1
AVISITN*TRTPN*SEX			M	10	2	1
AVISITN*TRTPN*SEX			F	10	3	
AVISITN*TRTPN*SEX			M	10	3	
AVISITN*TRTPN*SEX			F	10	900	
AVISITN*TRTPN*SEX			M	10	900	
AVISITN*TRTPN*SEX			F	12	1	
AVISITN*TRTPN*SEX			M	12	1	
AVISITN*TRTPN*SEX			F	12	2	
AVISITN*TRTPN*SEX			M	12	2	
AVISITN*TRTPN*SEX			F	12	3	
AVISITN*TRTPN*SEX			M	12	3	
AVISITN*TRTPN*SEX			F	12	900	
AVISITN*TRTPN*SEX			M	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Coefficients for Dummy X vs. Dummy Z BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						

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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
SEX			F			
SEX			M			
AVISITN*SEX			F	3		
AVISITN*SEX			M	3		
AVISITN*SEX			F	6		
AVISITN*SEX			M	6		
AVISITN*SEX			F	10		

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*SEX			M	10		
AVISITN*SEX			F	12		
AVISITN*SEX			M	12		
TRTPN*SEX			F		1	
TRTPN*SEX			M		1	
TRTPN*SEX			F		2	1
TRTPN*SEX			M		2	-1
TRTPN*SEX			F		3	
TRTPN*SEX			M		3	
TRTPN*SEX			F		900	-1
TRTPN*SEX			M		900	1
AVISITN*TRTPN*SEX			F	3	1	
AVISITN*TRTPN*SEX			M	3	1	
AVISITN*TRTPN*SEX			F	3	2	
AVISITN*TRTPN*SEX			M	3	2	
AVISITN*TRTPN*SEX			F	3	3	
AVISITN*TRTPN*SEX			M	3	3	
AVISITN*TRTPN*SEX			F	3	900	

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*SEX			M	3	900	
AVISITN*TRTPN*SEX			F	6	1	
AVISITN*TRTPN*SEX			M	6	1	
AVISITN*TRTPN*SEX			F	6	2	
AVISITN*TRTPN*SEX			M	6	2	
AVISITN*TRTPN*SEX			F	6	3	
AVISITN*TRTPN*SEX			M	6	3	
AVISITN*TRTPN*SEX			F	6	900	
AVISITN*TRTPN*SEX			M	6	900	
AVISITN*TRTPN*SEX			F	10	1	
AVISITN*TRTPN*SEX			M	10	1	
AVISITN*TRTPN*SEX			F	10	2	1
AVISITN*TRTPN*SEX			M	10	2	-1
AVISITN*TRTPN*SEX			F	10	3	
AVISITN*TRTPN*SEX			M	10	3	
AVISITN*TRTPN*SEX			F	10	900	-1
AVISITN*TRTPN*SEX			M	10	900	1
AVISITN*TRTPN*SEX			F	12	1	

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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*SEX			M	12	1	
AVISITN*TRTPN*SEX			F	12	2	
AVISITN*TRTPN*SEX			M	12	2	
AVISITN*TRTPN*SEX			F	12	3	
AVISITN*TRTPN*SEX			M	12	3	
AVISITN*TRTPN*SEX			F	12	900	
AVISITN*TRTPN*SEX			M	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY SEX AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
SEX			F			
SEX			M			
AVISITN*SEX			F	3		
AVISITN*SEX			M	3		
AVISITN*SEX			F	6		
AVISITN*SEX			M	6		
AVISITN*SEX			F	10		
AVISITN*SEX			M	10		
AVISITN*SEX			F	12		
AVISITN*SEX			M	12		
TRTPN*SEX			F		1	
TRTPN*SEX			M		1	
TRTPN*SEX			F		2	
TRTPN*SEX			M		2	
TRTPN*SEX			F		3	1
TRTPN*SEX			M		3	-1
TRTPN*SEX			F		900	-1

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STAT-3.1
MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*SEX			M		900	1
AVISITN*TRTPN*SEX			F	3	1	
AVISITN*TRTPN*SEX			M	3	1	
AVISITN*TRTPN*SEX			F	3	2	
AVISITN*TRTPN*SEX			M	3	2	
AVISITN*TRTPN*SEX			F	3	3	
AVISITN*TRTPN*SEX			M	3	3	
AVISITN*TRTPN*SEX			F	3	900	
AVISITN*TRTPN*SEX			M	3	900	
AVISITN*TRTPN*SEX			F	6	1	
AVISITN*TRTPN*SEX			M	6	1	
AVISITN*TRTPN*SEX			F	6	2	
AVISITN*TRTPN*SEX			M	6	2	
AVISITN*TRTPN*SEX			F	6	3	
AVISITN*TRTPN*SEX			M	6	3	
AVISITN*TRTPN*SEX			F	6	900	
AVISITN*TRTPN*SEX			M	6	900	
AVISITN*TRTPN*SEX			F	10	1	

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY SEX AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*SEX			M	10	1	
AVISITN*TRTPN*SEX			F	10	2	
AVISITN*TRTPN*SEX			M	10	2	
AVISITN*TRTPN*SEX			F	10	3	1
AVISITN*TRTPN*SEX			M	10	3	-1
AVISITN*TRTPN*SEX			F	10	900	-1
AVISITN*TRTPN*SEX			M	10	900	1
AVISITN*TRTPN*SEX			F	12	1	
AVISITN*TRTPN*SEX			M	12	1	
AVISITN*TRTPN*SEX			F	12	2	
AVISITN*TRTPN*SEX			M	12	2	
AVISITN*TRTPN*SEX			F	12	3	
AVISITN*TRTPN*SEX			M	12	3	
AVISITN*TRTPN*SEX			F	12	900	
AVISITN*TRTPN*SEX			M	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction
 (Intent to Treat Sample)

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The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY SEX AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Sex	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy W vs. Dummy Z BY SEX AT Phase B	-2.1308	3.9228	237	-0.54	0.5875
Dummy W vs. Dummy Y BY SEX AT Phase B	-4.2187	4.0938	238	-1.03	0.3038
Dummy W vs. Dummy X BY SEX AT Phase B	-3.2445	4.2280	243	-0.77	0.4436
Dummy X vs. Dummy Z BY SEX AT Phase B	1.1137	4.1553	241	0.27	0.7889
Dummy Y vs. Dummy Z BY SEX AT Phase B	2.0878	4.0160	238	0.52	0.6036

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Least Squares Means

Effect	Sex	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN*SEX	F	3	1	-6.7889	1.4561	289	-4.66	<.0001	0.05	-9.6548	-3.9231
AVISITN*TRTPN*SEX	M	3	1	-5.9658	1.6705	281	-3.57	0.0004	0.05	-9.2540	-2.6776
AVISITN*TRTPN*SEX	F	3	2	-3.5409	1.4928	291	-2.37	0.0183	0.05	-6.4789	-0.6028
AVISITN*TRTPN*SEX	M	3	2	-6.7014	1.8949	279	-3.54	0.0005	0.05	-10.4315	-2.9712
AVISITN*TRTPN*SEX	F	3	3	-5.8264	1.4309	285	-4.07	<.0001	0.05	-8.6430	-3.0099
AVISITN*TRTPN*SEX	M	3	3	-6.9685	1.7744	280	-3.93	0.0001	0.05	-10.4614	-3.4756
AVISITN*TRTPN*SEX	F	3	900	-6.9522	1.4980	288	-4.64	<.0001	0.05	-9.9007	-4.0038
AVISITN*TRTPN*SEX	M	3	900	-5.2610	1.5640	275	-3.36	0.0009	0.05	-8.3399	-2.1820
AVISITN*TRTPN*SEX	F	6	1	-12.3592	1.7951	299	-6.89	<.0001	0.05	-15.8918	-8.8267
AVISITN*TRTPN*SEX	M	6	1	-12.8657	2.0178	254	-6.38	<.0001	0.05	-16.8393	-8.8920
AVISITN*TRTPN*SEX	F	6	2	-7.2561	1.7864	299	-4.06	<.0001	0.05	-10.7716	-3.7405
AVISITN*TRTPN*SEX	M	6	2	-9.3923	2.3864	269	-3.94	0.0001	0.05	-14.0908	-4.6939
AVISITN*TRTPN*SEX	F	6	3	-10.5404	1.7494	297	-6.03	<.0001	0.05	-13.9832	-7.0977
AVISITN*TRTPN*SEX	M	6	3	-8.1657	2.2259	270	-3.67	0.0003	0.05	-12.5479	-3.7834
AVISITN*TRTPN*SEX	F	6	900	-9.8078	1.7951	296	-5.46	<.0001	0.05	-13.3405	-6.2750
AVISITN*TRTPN*SEX	M	6	900	-7.6519	1.9070	253	-4.01	<.0001	0.05	-11.4076	-3.8962
AVISITN*TRTPN*SEX	F	10	1	-18.0953	1.8948	262	-9.55	<.0001	0.05	-21.8262	-14.3644
AVISITN*TRTPN*SEX	M	10	1	-14.0253	2.1856	238	-6.42	<.0001	0.05	-18.3309	-9.7197
AVISITN*TRTPN*SEX	F	10	2	-12.5259	1.9553	288	-6.41	<.0001	0.05	-16.3744	-8.6774

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STAT-3.1
 MMRM Output for Test on Treatment by Gender Interaction
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The Mixed Procedure

Least Squares Means

Effect	Sex	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN*SEX	M	10	2	-11.7004	2.5767	246	-4.54	<.0001	0.05	-16.7755	-6.6253
AVISITN*TRTPN*SEX	F	10	3	-11.3659	1.8419	261	-6.17	<.0001	0.05	-14.9927	-7.7391
AVISITN*TRTPN*SEX	M	10	3	-11.5145	2.4232	248	-4.75	<.0001	0.05	-16.2872	-6.7419
AVISITN*TRTPN*SEX	F	10	900	-11.3087	1.9194	275	-5.89	<.0001	0.05	-15.0874	-7.5300
AVISITN*TRTPN*SEX	M	10	900	-9.3695	2.0402	232	-4.59	<.0001	0.05	-13.3893	-5.3498
AVISITN*TRTPN*SEX	F	12	1	-17.5671	2.0876	271	-8.41	<.0001	0.05	-21.6771	-13.4570
AVISITN*TRTPN*SEX	M	12	1	-16.8320	2.4007	238	-7.01	<.0001	0.05	-21.5613	-12.1026
AVISITN*TRTPN*SEX	F	12	2	-11.4103	2.1389	287	-5.33	<.0001	0.05	-15.6203	-7.2003
AVISITN*TRTPN*SEX	M	12	2	-13.9162	2.8294	246	-4.92	<.0001	0.05	-19.4891	-8.3432
AVISITN*TRTPN*SEX	F	12	3	-14.9148	2.0092	267	-7.42	<.0001	0.05	-18.8708	-10.9589
AVISITN*TRTPN*SEX	M	12	3	-14.9628	2.6369	243	-5.67	<.0001	0.05	-20.1570	-9.7687
AVISITN*TRTPN*SEX	F	12	900	-11.1977	2.0889	275	-5.36	<.0001	0.05	-15.3099	-7.0854
AVISITN*TRTPN*SEX	M	12	900	-12.2024	2.2546	238	-5.41	<.0001	0.05	-16.6440	-7.7609

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PROTOCOL 331-201-00061

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STAT-3.2
MMRM Output for Test on Treatment by Race Interaction
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
AVISITN	4	3 6 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	
COMBFL	2	N Y

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STAT-3.2
MMRM Output for Test on Treatment by Race Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	299	

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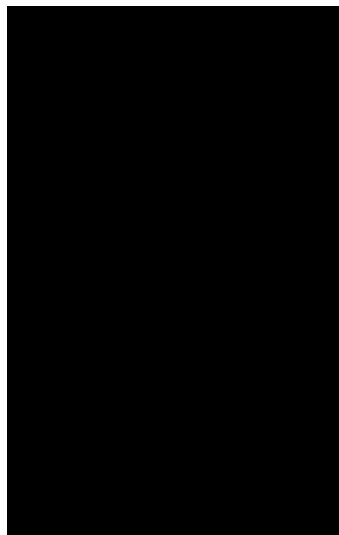
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----- Parameter Code=CAPSTOT -----

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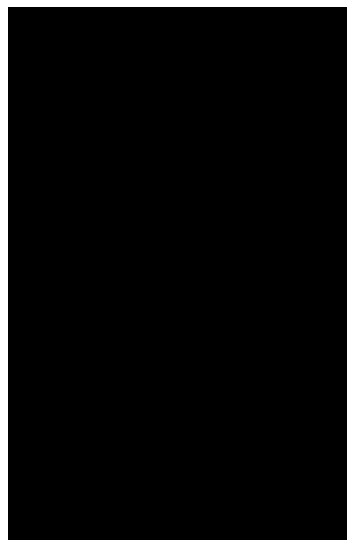
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STAT-3.2
MMRM Output for Test on Treatment by Race Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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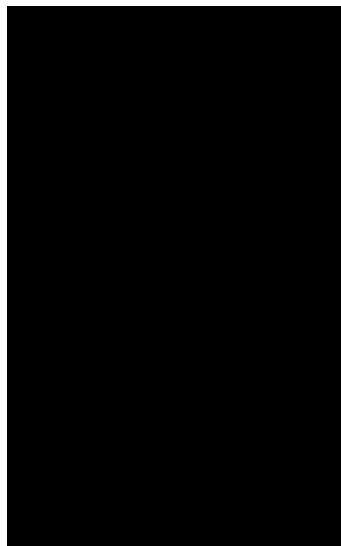
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STAT-3.2
MMRM Output for Test on Treatment by Race Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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STAT-3.2
MMRM Output for Test on Treatment by Race Interaction
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

RACEGRP 2 All Other Races White

Dimensions

Covariance Parameters	10
Columns in X	91
Columns in Z	0
Subjects	299
Max Obs per Subject	4

Number of Observations

Number of Observations Read	996
Number of Observations Used	996
Number of Observations Not Used	0

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STAT-3.2
MMRM Output for Test on Treatment by Race Interaction
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----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	7344.39769030	
1	2	6876.20343728	0.00090786
2	1	6873.54971090	0.00005851
3	1	6873.39279538	0.00000031
4	1	6873.39198966	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	77.5638
UN(2,1)	SUBJID	52.8666
UN(2,2)	SUBJID	114.95
UN(3,1)	SUBJID	42.8865
UN(3,2)	SUBJID	90.0751
UN(3,3)	SUBJID	124.37
UN(4,1)	SUBJID	48.8023

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STAT-3.2
MMRM Output for Test on Treatment by Race Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,2)	SUBJID	91.3636
UN(4,3)	SUBJID	106.14
UN(4,4)	SUBJID	149.07

Fit Statistics

-2 Res Log Likelihood	6873.4
AIC (Smaller is Better)	6893.4
AICC (Smaller is Better)	6893.6
BIC (Smaller is Better)	6930.4

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
9	471.01	<.0001

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STAT-3.2
MMRM Output for Test on Treatment by Race Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
POOLCNTR	9	276	1.43	0.1759
COMBFL	1	277	3.87	0.0502
AVISITN	3	226	0.80	0.4937
TRTPN	3	262	2.12	0.0978
AVISITN*TRTPN	9	359	2.07	0.0315
RACEGRP	1	270	0.15	0.6951
AVISITN*RACEGRP	3	234	0.61	0.6066
TRTPN*RACEGRP	3	262	0.48	0.6967
AVISITN*TRTPN*RACEGRP	9	359	0.70	0.7068
BASE*AVISITN	4	237	14.95	<.0001

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STAT-3.2
MMRM Output for Test on Treatment by Race Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY RACEGRP AT Phase B Week 10

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY RACEGRP AT Phase B Week 10

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY RACEGRP AT Phase B Week 10

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
RACEGRP			All Other Races			
RACEGRP			White			
AVISITN*RACEGRP			All Other Races	3		
AVISITN*RACEGRP			White	3		
AVISITN*RACEGRP			All Other Races	6		
AVISITN*RACEGRP			White	6		
AVISITN*RACEGRP			All Other Races	10		
AVISITN*RACEGRP			White	10		
AVISITN*RACEGRP			All Other Races	12		
AVISITN*RACEGRP			White	12		
TRTPN*RACEGRP			All Other Races		1	1
TRTPN*RACEGRP			White		1	-1
TRTPN*RACEGRP			All Other Races		2	
TRTPN*RACEGRP			White		2	
TRTPN*RACEGRP			All Other Races		3	
TRTPN*RACEGRP			White		3	
TRTPN*RACEGRP			All Other Races		900	-1

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*RACEGRP			White		900	1
AVISIT*TRTPN*RACEGRP			All Other Races	3	1	
AVISIT*TRTPN*RACEGRP			White	3	1	
AVISIT*TRTPN*RACEGRP			All Other Races	3	2	
AVISIT*TRTPN*RACEGRP			White	3	2	
AVISIT*TRTPN*RACEGRP			All Other Races	3	3	
AVISIT*TRTPN*RACEGRP			White	3	3	
AVISIT*TRTPN*RACEGRP			All Other Races	3	900	
AVISIT*TRTPN*RACEGRP			White	3	900	
AVISIT*TRTPN*RACEGRP			All Other Races	6	1	
AVISIT*TRTPN*RACEGRP			White	6	1	
AVISIT*TRTPN*RACEGRP			All Other Races	6	2	
AVISIT*TRTPN*RACEGRP			White	6	2	
AVISIT*TRTPN*RACEGRP			All Other Races	6	3	
AVISIT*TRTPN*RACEGRP			White	6	3	
AVISIT*TRTPN*RACEGRP			All Other Races	6	900	
AVISIT*TRTPN*RACEGRP			White	6	900	
AVISIT*TRTPN*RACEGRP			All Other Races	10	1	1

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*RACEGRP			White	10	1	-1
AVISIT*TRTPN*RACEGRP			All Other Races	10	2	
AVISIT*TRTPN*RACEGRP			White	10	2	
AVISIT*TRTPN*RACEGRP			All Other Races	10	3	
AVISIT*TRTPN*RACEGRP			White	10	3	
AVISIT*TRTPN*RACEGRP			All Other Races	10	900	-1
AVISIT*TRTPN*RACEGRP			White	10	900	1
AVISIT*TRTPN*RACEGRP			All Other Races	12	1	
AVISIT*TRTPN*RACEGRP			White	12	1	
AVISIT*TRTPN*RACEGRP			All Other Races	12	2	
AVISIT*TRTPN*RACEGRP			White	12	2	
AVISIT*TRTPN*RACEGRP			All Other Races	12	3	
AVISIT*TRTPN*RACEGRP			White	12	3	
AVISIT*TRTPN*RACEGRP			All Other Races	12	900	
AVISIT*TRTPN*RACEGRP			White	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.2
MMRM Output for Test on Treatment by Race Interaction
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Coefficients for Dummy W vs. Dummy Y BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						

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STAT-3.2
MMRM Output for Test on Treatment by Race Interaction
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
RACEGRP			All Other Races			
RACEGRP			White			
AVISITN*RACEGRP			All Other Races	3		
AVISITN*RACEGRP			White	3		
AVISITN*RACEGRP			All Other Races	6		
AVISITN*RACEGRP			White	6		
AVISITN*RACEGRP			All Other Races	10		

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*RACEGRP			White	10		
AVISITN*RACEGRP			All Other Races	12		
AVISITN*RACEGRP			White	12		
TRTPN*RACEGRP			All Other Races		1	1
TRTPN*RACEGRP			White		1	-1
TRTPN*RACEGRP			All Other Races		2	
TRTPN*RACEGRP			White		2	
TRTPN*RACEGRP			All Other Races		3	-1
TRTPN*RACEGRP			White		3	1
TRTPN*RACEGRP			All Other Races		900	
TRTPN*RACEGRP			White		900	
AVISIT*TRTPN*RACEGRP			All Other Races	3	1	
AVISIT*TRTPN*RACEGRP			White	3	1	
AVISIT*TRTPN*RACEGRP			All Other Races	3	2	
AVISIT*TRTPN*RACEGRP			White	3	2	
AVISIT*TRTPN*RACEGRP			All Other Races	3	3	
AVISIT*TRTPN*RACEGRP			White	3	3	
AVISIT*TRTPN*RACEGRP			All Other Races	3	900	

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*RACEGRP			White	3	900	
AVISIT*TRTPN*RACEGRP			All Other Races	6	1	
AVISIT*TRTPN*RACEGRP			White	6	1	
AVISIT*TRTPN*RACEGRP			All Other Races	6	2	
AVISIT*TRTPN*RACEGRP			White	6	2	
AVISIT*TRTPN*RACEGRP			All Other Races	6	3	
AVISIT*TRTPN*RACEGRP			White	6	3	
AVISIT*TRTPN*RACEGRP			All Other Races	6	900	
AVISIT*TRTPN*RACEGRP			White	6	900	
AVISIT*TRTPN*RACEGRP			All Other Races	10	1	1
AVISIT*TRTPN*RACEGRP			White	10	1	-1
AVISIT*TRTPN*RACEGRP			All Other Races	10	2	
AVISIT*TRTPN*RACEGRP			White	10	2	
AVISIT*TRTPN*RACEGRP			All Other Races	10	3	-1
AVISIT*TRTPN*RACEGRP			White	10	3	1
AVISIT*TRTPN*RACEGRP			All Other Races	10	900	
AVISIT*TRTPN*RACEGRP			White	10	900	
AVISIT*TRTPN*RACEGRP			All Other Races	12	1	

FILE: stat2b.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*RACEGRP			White	12	1	
AVISIT*TRTPN*RACEGRP			All Other Races	12	2	
AVISIT*TRTPN*RACEGRP			White	12	2	
AVISIT*TRTPN*RACEGRP			All Other Races	12	3	
AVISIT*TRTPN*RACEGRP			White	12	3	
AVISIT*TRTPN*RACEGRP			All Other Races	12	900	
AVISIT*TRTPN*RACEGRP			White	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.2
MMRM Output for Test on Treatment by Race Interaction
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.2
MMRM Output for Test on Treatment by Race Interaction
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
RACEGRP			All Other Races			
RACEGRP			White			
AVISITN*RACEGRP			All Other Races	3		
AVISITN*RACEGRP			White	3		
AVISITN*RACEGRP			All Other Races	6		
AVISITN*RACEGRP			White	6		
AVISITN*RACEGRP			All Other Races	10		
AVISITN*RACEGRP			White	10		
AVISITN*RACEGRP			All Other Races	12		
AVISITN*RACEGRP			White	12		
TRTPN*RACEGRP			All Other Races		1	1
TRTPN*RACEGRP			White		1	-1
TRTPN*RACEGRP			All Other Races		2	-1
TRTPN*RACEGRP			White		2	1
TRTPN*RACEGRP			All Other Races		3	
TRTPN*RACEGRP			White		3	
TRTPN*RACEGRP			All Other Races		900	

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*RACEGRP			White		900	
AVISIT*TRTPN*RACEGRP			All Other Races	3	1	
AVISIT*TRTPN*RACEGRP			White	3	1	
AVISIT*TRTPN*RACEGRP			All Other Races	3	2	
AVISIT*TRTPN*RACEGRP			White	3	2	
AVISIT*TRTPN*RACEGRP			All Other Races	3	3	
AVISIT*TRTPN*RACEGRP			White	3	3	
AVISIT*TRTPN*RACEGRP			All Other Races	3	900	
AVISIT*TRTPN*RACEGRP			White	3	900	
AVISIT*TRTPN*RACEGRP			All Other Races	6	1	
AVISIT*TRTPN*RACEGRP			White	6	1	
AVISIT*TRTPN*RACEGRP			All Other Races	6	2	
AVISIT*TRTPN*RACEGRP			White	6	2	
AVISIT*TRTPN*RACEGRP			All Other Races	6	3	
AVISIT*TRTPN*RACEGRP			White	6	3	
AVISIT*TRTPN*RACEGRP			All Other Races	6	900	
AVISIT*TRTPN*RACEGRP			White	6	900	
AVISIT*TRTPN*RACEGRP			All Other Races	10	1	1

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*RACEGRP			White	10	1	-1
AVISIT*TRTPN*RACEGRP			All Other Races	10	2	-1
AVISIT*TRTPN*RACEGRP			White	10	2	1
AVISIT*TRTPN*RACEGRP			All Other Races	10	3	
AVISIT*TRTPN*RACEGRP			White	10	3	
AVISIT*TRTPN*RACEGRP			All Other Races	10	900	
AVISIT*TRTPN*RACEGRP			White	10	900	
AVISIT*TRTPN*RACEGRP			All Other Races	12	1	
AVISIT*TRTPN*RACEGRP			White	12	1	
AVISIT*TRTPN*RACEGRP			All Other Races	12	2	
AVISIT*TRTPN*RACEGRP			White	12	2	
AVISIT*TRTPN*RACEGRP			All Other Races	12	3	
AVISIT*TRTPN*RACEGRP			White	12	3	
AVISIT*TRTPN*RACEGRP			All Other Races	12	900	
AVISIT*TRTPN*RACEGRP			White	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.2
MMRM Output for Test on Treatment by Race Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Coefficients for Dummy X vs. Dummy Z BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
RACEGRP			All Other Races			
RACEGRP			White			
AVISITN*RACEGRP			All Other Races	3		
AVISITN*RACEGRP			White	3		
AVISITN*RACEGRP			All Other Races	6		
AVISITN*RACEGRP			White	6		
AVISITN*RACEGRP			All Other Races	10		

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*RACEGRP			White	10		
AVISITN*RACEGRP			All Other Races	12		
AVISITN*RACEGRP			White	12		
TRTPN*RACEGRP			All Other Races		1	
TRTPN*RACEGRP			White		1	
TRTPN*RACEGRP			All Other Races		2	1
TRTPN*RACEGRP			White		2	-1
TRTPN*RACEGRP			All Other Races		3	
TRTPN*RACEGRP			White		3	
TRTPN*RACEGRP			All Other Races		900	-1
TRTPN*RACEGRP			White		900	1
AVISIT*TRTPN*RACEGRP			All Other Races	3	1	
AVISIT*TRTPN*RACEGRP			White	3	1	
AVISIT*TRTPN*RACEGRP			All Other Races	3	2	
AVISIT*TRTPN*RACEGRP			White	3	2	
AVISIT*TRTPN*RACEGRP			All Other Races	3	3	
AVISIT*TRTPN*RACEGRP			White	3	3	
AVISIT*TRTPN*RACEGRP			All Other Races	3	900	

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*RACEGRP			White	3	900	
AVISIT*TRTPN*RACEGRP			All Other Races	6	1	
AVISIT*TRTPN*RACEGRP			White	6	1	
AVISIT*TRTPN*RACEGRP			All Other Races	6	2	
AVISIT*TRTPN*RACEGRP			White	6	2	
AVISIT*TRTPN*RACEGRP			All Other Races	6	3	
AVISIT*TRTPN*RACEGRP			White	6	3	
AVISIT*TRTPN*RACEGRP			All Other Races	6	900	
AVISIT*TRTPN*RACEGRP			White	6	900	
AVISIT*TRTPN*RACEGRP			All Other Races	10	1	
AVISIT*TRTPN*RACEGRP			White	10	1	
AVISIT*TRTPN*RACEGRP			All Other Races	10	2	1
AVISIT*TRTPN*RACEGRP			White	10	2	-1
AVISIT*TRTPN*RACEGRP			All Other Races	10	3	
AVISIT*TRTPN*RACEGRP			White	10	3	
AVISIT*TRTPN*RACEGRP			All Other Races	10	900	-1
AVISIT*TRTPN*RACEGRP			White	10	900	1
AVISIT*TRTPN*RACEGRP			All Other Races	12	1	

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The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*RACEGRP			White	12	1	
AVISIT*TRTPN*RACEGRP			All Other Races	12	2	
AVISIT*TRTPN*RACEGRP			White	12	2	
AVISIT*TRTPN*RACEGRP			All Other Races	12	3	
AVISIT*TRTPN*RACEGRP			White	12	3	
AVISIT*TRTPN*RACEGRP			All Other Races	12	900	
AVISIT*TRTPN*RACEGRP			White	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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 (Intent to Treat Sample)

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The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
RACEGRP			All Other Races			
RACEGRP			White			
AVISITN*RACEGRP			All Other Races	3		
AVISITN*RACEGRP			White	3		
AVISITN*RACEGRP			All Other Races	6		
AVISITN*RACEGRP			White	6		
AVISITN*RACEGRP			All Other Races	10		
AVISITN*RACEGRP			White	10		
AVISITN*RACEGRP			All Other Races	12		
AVISITN*RACEGRP			White	12		
TRTPN*RACEGRP			All Other Races		1	
TRTPN*RACEGRP			White		1	
TRTPN*RACEGRP			All Other Races		2	
TRTPN*RACEGRP			White		2	
TRTPN*RACEGRP			All Other Races		3	1
TRTPN*RACEGRP			White		3	-1
TRTPN*RACEGRP			All Other Races		900	-1

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*RACEGRP			White		900	1
AVISIT*TRTPN*RACEGRP			All Other Races	3	1	
AVISIT*TRTPN*RACEGRP			White	3	1	
AVISIT*TRTPN*RACEGRP			All Other Races	3	2	
AVISIT*TRTPN*RACEGRP			White	3	2	
AVISIT*TRTPN*RACEGRP			All Other Races	3	3	
AVISIT*TRTPN*RACEGRP			White	3	3	
AVISIT*TRTPN*RACEGRP			All Other Races	3	900	
AVISIT*TRTPN*RACEGRP			White	3	900	
AVISIT*TRTPN*RACEGRP			All Other Races	6	1	
AVISIT*TRTPN*RACEGRP			White	6	1	
AVISIT*TRTPN*RACEGRP			All Other Races	6	2	
AVISIT*TRTPN*RACEGRP			White	6	2	
AVISIT*TRTPN*RACEGRP			All Other Races	6	3	
AVISIT*TRTPN*RACEGRP			White	6	3	
AVISIT*TRTPN*RACEGRP			All Other Races	6	900	
AVISIT*TRTPN*RACEGRP			White	6	900	
AVISIT*TRTPN*RACEGRP			All Other Races	10	1	

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*RACEGRP			White	10	1	
AVISIT*TRTPN*RACEGRP			All Other Races	10	2	
AVISIT*TRTPN*RACEGRP			White	10	2	
AVISIT*TRTPN*RACEGRP			All Other Races	10	3	1
AVISIT*TRTPN*RACEGRP			White	10	3	-1
AVISIT*TRTPN*RACEGRP			All Other Races	10	900	-1
AVISIT*TRTPN*RACEGRP			White	10	900	1
AVISIT*TRTPN*RACEGRP			All Other Races	12	1	
AVISIT*TRTPN*RACEGRP			White	12	1	
AVISIT*TRTPN*RACEGRP			All Other Races	12	2	
AVISIT*TRTPN*RACEGRP			White	12	2	
AVISIT*TRTPN*RACEGRP			All Other Races	12	3	
AVISIT*TRTPN*RACEGRP			White	12	3	
AVISIT*TRTPN*RACEGRP			All Other Races	12	900	
AVISIT*TRTPN*RACEGRP			White	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY RACEGRP AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy W vs. Dummy Z BY RACEGRP AT Phase B	2.2296	3.9796	233	0.56	0.5758
Dummy W vs. Dummy Y BY RACEGRP AT Phase B	3.8513	4.1388	231	0.93	0.3531
Dummy W vs. Dummy X BY RACEGRP AT Phase B	6.0188	4.1825	239	1.44	0.1514
Dummy X vs. Dummy Z BY RACEGRP AT Phase B	-3.7892	4.0544	239	-0.93	0.3509
Dummy Y vs. Dummy Z BY RACEGRP AT Phase B	-1.6217	4.0225	234	-0.40	0.6872

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Least Squares Means

Effect	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*RACEGRP	All Other Races	3	1	-3.7243	1.7733	282	-2.10	0.0366	0.05	-7.2149	-0.2336
AVISIT*TRTPN*RACEGRP	White	3	1	-7.9456	1.3273	282	-5.99	<.0001	0.05	-10.5584	-5.3329
AVISIT*TRTPN*RACEGRP	All Other Races	3	2	-5.4986	1.6869	282	-3.26	0.0013	0.05	-8.8192	-2.1780
AVISIT*TRTPN*RACEGRP	White	3	2	-3.7950	1.5221	284	-2.49	0.0132	0.05	-6.7910	-0.7990
AVISIT*TRTPN*RACEGRP	All Other Races	3	3	-4.8461	1.7959	277	-2.70	0.0074	0.05	-8.3814	-1.3108
AVISIT*TRTPN*RACEGRP	White	3	3	-6.9219	1.3452	281	-5.15	<.0001	0.05	-9.5698	-4.2739
AVISIT*TRTPN*RACEGRP	All Other Races	3	900	-6.4012	1.5465	279	-4.14	<.0001	0.05	-9.4456	-3.3569
AVISIT*TRTPN*RACEGRP	White	3	900	-6.0820	1.4324	280	-4.25	<.0001	0.05	-8.9017	-3.2623
AVISIT*TRTPN*RACEGRP	All Other Races	6	1	-11.7027	2.1912	261	-5.34	<.0001	0.05	-16.0174	-7.3880
AVISIT*TRTPN*RACEGRP	White	6	1	-13.0881	1.6668	276	-7.85	<.0001	0.05	-16.3694	-9.8068
AVISIT*TRTPN*RACEGRP	All Other Races	6	2	-8.0389	2.1519	291	-3.74	0.0002	0.05	-12.2741	-3.8037
AVISIT*TRTPN*RACEGRP	White	6	2	-7.8701	1.8584	270	-4.23	<.0001	0.05	-11.5289	-4.2113
AVISIT*TRTPN*RACEGRP	All Other Races	6	3	-8.9561	2.3820	296	-3.76	0.0002	0.05	-13.6438	-4.2683
AVISIT*TRTPN*RACEGRP	White	6	3	-9.9980	1.6551	269	-6.04	<.0001	0.05	-13.2566	-6.7394
AVISIT*TRTPN*RACEGRP	All Other Races	6	900	-8.8865	1.9191	271	-4.63	<.0001	0.05	-12.6648	-5.1083
AVISIT*TRTPN*RACEGRP	White	6	900	-8.9195	1.7485	261	-5.10	<.0001	0.05	-12.3624	-5.4765
AVISIT*TRTPN*RACEGRP	All Other Races	10	1	-13.9790	2.3550	238	-5.94	<.0001	0.05	-18.6184	-9.3396
AVISIT*TRTPN*RACEGRP	White	10	1	-17.7665	1.7633	241	-10.08	<.0001	0.05	-21.2401	-14.2930
AVISIT*TRTPN*RACEGRP	All Other Races	10	2	-13.4589	2.3418	270	-5.75	<.0001	0.05	-18.0693	-8.8484

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STAT-3.2
 MMRM Output for Test on Treatment by Race Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Least Squares Means

Effect	RACEGRP	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*RACEGRP	White	10	2	-11.2275	2.0250	255	-5.54	<.0001	0.05	-15.2154	-7.2397
AVISIT*TRTPN*RACEGRP	All Other Races	10	3	-11.3492	2.4400	241	-4.65	<.0001	0.05	-16.1556	-6.5428
AVISIT*TRTPN*RACEGRP	White	10	3	-11.2854	1.7825	247	-6.33	<.0001	0.05	-14.7963	-7.7745
AVISIT*TRTPN*RACEGRP	All Other Races	10	900	-9.6251	2.0179	241	-4.77	<.0001	0.05	-13.6001	-5.6502
AVISIT*TRTPN*RACEGRP	White	10	900	-11.1830	1.8892	245	-5.92	<.0001	0.05	-14.9041	-7.4619
AVISIT*TRTPN*RACEGRP	All Other Races	12	1	-16.5991	2.6071	246	-6.37	<.0001	0.05	-21.7342	-11.4640
AVISIT*TRTPN*RACEGRP	White	12	1	-17.6900	1.9430	247	-9.10	<.0001	0.05	-21.5169	-13.8631
AVISIT*TRTPN*RACEGRP	All Other Races	12	2	-12.6750	2.5704	269	-4.93	<.0001	0.05	-17.7357	-7.6143
AVISIT*TRTPN*RACEGRP	White	12	2	-11.8728	2.2224	256	-5.34	<.0001	0.05	-16.2493	-7.4964
AVISIT*TRTPN*RACEGRP	All Other Races	12	3	-16.6030	2.6362	239	-6.30	<.0001	0.05	-21.7962	-11.4099
AVISIT*TRTPN*RACEGRP	White	12	3	-13.8895	1.9603	251	-7.09	<.0001	0.05	-17.7502	-10.0289
AVISIT*TRTPN*RACEGRP	All Other Races	12	900	-11.6305	2.2073	246	-5.27	<.0001	0.05	-15.9782	-7.2829
AVISIT*TRTPN*RACEGRP	White	12	900	-11.7595	2.0830	251	-5.65	<.0001	0.05	-15.8618	-7.6571

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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
AVISITN	4	3 6 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	[REDACTED]
COMBFL	2	N Y

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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	299	[REDACTED]

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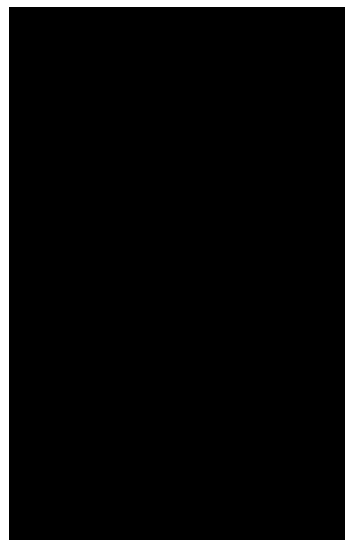
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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
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The Mixed Procedure



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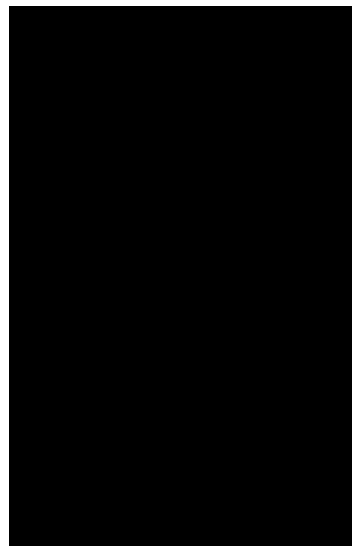
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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

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The Mixed Procedure



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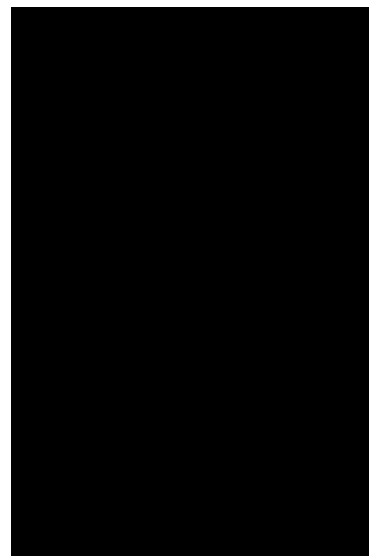
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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

AGEGRP 2 <55 >=55 [REDACTED]

Dimensions

Covariance Parameters	10
Columns in X	91
Columns in Z	0
Subjects	299
Max Obs per Subject	4

Number of Observations

Number of Observations Read	996
Number of Observations Used	996
Number of Observations Not Used	0

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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	7335.56990357	
1	2	6863.74324538	0.00071726
2	1	6861.67356308	0.00003735
3	1	6861.57448148	0.00000013
4	1	6861.57415440	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	77.8543
UN(2,1)	SUBJID	53.5922
UN(2,2)	SUBJID	114.49
UN(3,1)	SUBJID	44.6224
UN(3,2)	SUBJID	90.7193
UN(3,3)	SUBJID	125.79
UN(4,1)	SUBJID	48.6619

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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,2)	SUBJID	90.5499
UN(4,3)	SUBJID	105.79
UN(4,4)	SUBJID	147.93

Fit Statistics

-2 Res Log Likelihood	6861.6
AIC (Smaller is Better)	6881.6
AICC (Smaller is Better)	6881.8
BIC (Smaller is Better)	6918.6

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
9	474.00	<.0001

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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
POOLCNTR	9	277	1.61	0.1108
COMBFL	1	278	4.63	0.0323
AVISITN	3	228	0.28	0.8367
TRTPN	3	266	2.26	0.0821
AVISITN*TRTPN	9	358	1.29	0.2410
AGEGRP	1	271	0.19	0.6638
AVISITN*AGEGRP	3	235	1.16	0.3240
TRTPN*AGEGRP	3	265	0.98	0.4046
AVISITN*TRTPN*AGEGRP	9	359	0.73	0.6787
BASE*AVISITN	4	239	15.02	<.0001

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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL	[REDACTED]	N				
COMBFL	[REDACTED]	Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

FILE: stat2c.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
AGEGRP			<55			
AGEGRP			>=55			
AVISITN*AGEGRP			<55	3		
AVISITN*AGEGRP			>=55	3		
AVISITN*AGEGRP			<55	6		
AVISITN*AGEGRP			>=55	6		
AVISITN*AGEGRP			<55	10		
AVISITN*AGEGRP			>=55	10		
AVISITN*AGEGRP			<55	12		
AVISITN*AGEGRP			>=55	12		
TRTPN*AGEGRP			<55		1	1
TRTPN*AGEGRP			>=55		1	-1
TRTPN*AGEGRP			<55		2	
TRTPN*AGEGRP			>=55		2	
TRTPN*AGEGRP			<55		3	
TRTPN*AGEGRP			>=55		3	
TRTPN*AGEGRP			<55		900	-1

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*AGEGRP			>=55		900	1
AVISITN*TRTPN*AGEGRP			<55	3	1	
AVISITN*TRTPN*AGEGRP			>=55	3	1	
AVISITN*TRTPN*AGEGRP			<55	3	2	
AVISITN*TRTPN*AGEGRP			>=55	3	2	
AVISITN*TRTPN*AGEGRP			<55	3	3	
AVISITN*TRTPN*AGEGRP			>=55	3	3	
AVISITN*TRTPN*AGEGRP			<55	3	900	
AVISITN*TRTPN*AGEGRP			>=55	3	900	
AVISITN*TRTPN*AGEGRP			<55	6	1	
AVISITN*TRTPN*AGEGRP			>=55	6	1	
AVISITN*TRTPN*AGEGRP			<55	6	2	
AVISITN*TRTPN*AGEGRP			>=55	6	2	
AVISITN*TRTPN*AGEGRP			<55	6	3	
AVISITN*TRTPN*AGEGRP			>=55	6	3	
AVISITN*TRTPN*AGEGRP			<55	6	900	
AVISITN*TRTPN*AGEGRP			>=55	6	900	
AVISITN*TRTPN*AGEGRP			<55	10	1	1

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*AGEGRP			>=55	10	1	-1
AVISITN*TRTPN*AGEGRP			<55	10	2	
AVISITN*TRTPN*AGEGRP			>=55	10	2	
AVISITN*TRTPN*AGEGRP			<55	10	3	
AVISITN*TRTPN*AGEGRP			>=55	10	3	
AVISITN*TRTPN*AGEGRP			<55	10	900	-1
AVISITN*TRTPN*AGEGRP			>=55	10	900	1
AVISITN*TRTPN*AGEGRP			<55	12	1	
AVISITN*TRTPN*AGEGRP			>=55	12	1	
AVISITN*TRTPN*AGEGRP			<55	12	2	
AVISITN*TRTPN*AGEGRP			>=55	12	2	
AVISITN*TRTPN*AGEGRP			<55	12	3	
AVISITN*TRTPN*AGEGRP			>=55	12	3	
AVISITN*TRTPN*AGEGRP			<55	12	900	
AVISITN*TRTPN*AGEGRP			>=55	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Coefficients for Dummy W vs. Dummy Y BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
AGEGRP			<55			
AGEGRP			>=55			
AVISITN*AGEGRP			<55	3		
AVISITN*AGEGRP			>=55	3		
AVISITN*AGEGRP			<55	6		
AVISITN*AGEGRP			>=55	6		
AVISITN*AGEGRP			<55	10		

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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*AGEGRP			>=55	10		
AVISITN*AGEGRP			<55	12		
AVISITN*AGEGRP			>=55	12		
TRTPN*AGEGRP			<55		1	1
TRTPN*AGEGRP			>=55		1	-1
TRTPN*AGEGRP			<55		2	
TRTPN*AGEGRP			>=55		2	
TRTPN*AGEGRP			<55		3	-1
TRTPN*AGEGRP			>=55		3	1
TRTPN*AGEGRP			<55		900	
TRTPN*AGEGRP			>=55		900	
AVISITN*TRTPN*AGEGRP			<55	3	1	
AVISITN*TRTPN*AGEGRP			>=55	3	1	
AVISITN*TRTPN*AGEGRP			<55	3	2	
AVISITN*TRTPN*AGEGRP			>=55	3	2	
AVISITN*TRTPN*AGEGRP			<55	3	3	
AVISITN*TRTPN*AGEGRP			>=55	3	3	
AVISITN*TRTPN*AGEGRP			<55	3	900	

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*AGEGRP			>=55	3	900	
AVISITN*TRTPN*AGEGRP			<55	6	1	
AVISITN*TRTPN*AGEGRP			>=55	6	1	
AVISITN*TRTPN*AGEGRP			<55	6	2	
AVISITN*TRTPN*AGEGRP			>=55	6	2	
AVISITN*TRTPN*AGEGRP			<55	6	3	
AVISITN*TRTPN*AGEGRP			>=55	6	3	
AVISITN*TRTPN*AGEGRP			<55	6	900	
AVISITN*TRTPN*AGEGRP			>=55	6	900	
AVISITN*TRTPN*AGEGRP			<55	10	1	1
AVISITN*TRTPN*AGEGRP			>=55	10	1	-1
AVISITN*TRTPN*AGEGRP			<55	10	2	
AVISITN*TRTPN*AGEGRP			>=55	10	2	
AVISITN*TRTPN*AGEGRP			<55	10	3	-1
AVISITN*TRTPN*AGEGRP			>=55	10	3	1
AVISITN*TRTPN*AGEGRP			<55	10	900	
AVISITN*TRTPN*AGEGRP			>=55	10	900	
AVISITN*TRTPN*AGEGRP			<55	12	1	

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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*AGEGRP			>=55	12	1	
AVISITN*TRTPN*AGEGRP			<55	12	2	
AVISITN*TRTPN*AGEGRP			>=55	12	2	
AVISITN*TRTPN*AGEGRP			<55	12	3	
AVISITN*TRTPN*AGEGRP			>=55	12	3	
AVISITN*TRTPN*AGEGRP			<55	12	900	
AVISITN*TRTPN*AGEGRP			>=55	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
AGEGRP			<55			
AGEGRP			>=55			
AVISITN*AGEGRP			<55	3		
AVISITN*AGEGRP			>=55	3		
AVISITN*AGEGRP			<55	6		
AVISITN*AGEGRP			>=55	6		
AVISITN*AGEGRP			<55	10		
AVISITN*AGEGRP			>=55	10		
AVISITN*AGEGRP			<55	12		
AVISITN*AGEGRP			>=55	12		
TRTPN*AGEGRP			<55		1	1
TRTPN*AGEGRP			>=55		1	-1
TRTPN*AGEGRP			<55		2	-1
TRTPN*AGEGRP			>=55		2	1
TRTPN*AGEGRP			<55		3	
TRTPN*AGEGRP			>=55		3	
TRTPN*AGEGRP			<55		900	

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*AGEGRP			>=55		900	
AVISITN*TRTPN*AGEGRP			<55	3	1	
AVISITN*TRTPN*AGEGRP			>=55	3	1	
AVISITN*TRTPN*AGEGRP			<55	3	2	
AVISITN*TRTPN*AGEGRP			>=55	3	2	
AVISITN*TRTPN*AGEGRP			<55	3	3	
AVISITN*TRTPN*AGEGRP			>=55	3	3	
AVISITN*TRTPN*AGEGRP			<55	3	900	
AVISITN*TRTPN*AGEGRP			>=55	3	900	
AVISITN*TRTPN*AGEGRP			<55	6	1	
AVISITN*TRTPN*AGEGRP			>=55	6	1	
AVISITN*TRTPN*AGEGRP			<55	6	2	
AVISITN*TRTPN*AGEGRP			>=55	6	2	
AVISITN*TRTPN*AGEGRP			<55	6	3	
AVISITN*TRTPN*AGEGRP			>=55	6	3	
AVISITN*TRTPN*AGEGRP			<55	6	900	
AVISITN*TRTPN*AGEGRP			>=55	6	900	
AVISITN*TRTPN*AGEGRP			<55	10	1	1

FILE: stat2c.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*AGEGRP			>=55	10	1	-1
AVISITN*TRTPN*AGEGRP			<55	10	2	-1
AVISITN*TRTPN*AGEGRP			>=55	10	2	1
AVISITN*TRTPN*AGEGRP			<55	10	3	
AVISITN*TRTPN*AGEGRP			>=55	10	3	
AVISITN*TRTPN*AGEGRP			<55	10	900	
AVISITN*TRTPN*AGEGRP			>=55	10	900	
AVISITN*TRTPN*AGEGRP			<55	12	1	
AVISITN*TRTPN*AGEGRP			>=55	12	1	
AVISITN*TRTPN*AGEGRP			<55	12	2	
AVISITN*TRTPN*AGEGRP			>=55	12	2	
AVISITN*TRTPN*AGEGRP			<55	12	3	
AVISITN*TRTPN*AGEGRP			>=55	12	3	
AVISITN*TRTPN*AGEGRP			<55	12	900	
AVISITN*TRTPN*AGEGRP			>=55	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Coefficients for Dummy X vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
AGEGRP			<55			
AGEGRP			>=55			
AVISITN*AGEGRP			<55	3		
AVISITN*AGEGRP			>=55	3		
AVISITN*AGEGRP			<55	6		
AVISITN*AGEGRP			>=55	6		
AVISITN*AGEGRP			<55	10		

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*AGEGRP			>=55	10		
AVISITN*AGEGRP			<55	12		
AVISITN*AGEGRP			>=55	12		
TRTPN*AGEGRP			<55		1	
TRTPN*AGEGRP			>=55		1	
TRTPN*AGEGRP			<55		2	1
TRTPN*AGEGRP			>=55		2	-1
TRTPN*AGEGRP			<55		3	
TRTPN*AGEGRP			>=55		3	
TRTPN*AGEGRP			<55		900	-1
TRTPN*AGEGRP			>=55		900	1
AVISITN*TRTPN*AGEGRP			<55	3	1	
AVISITN*TRTPN*AGEGRP			>=55	3	1	
AVISITN*TRTPN*AGEGRP			<55	3	2	
AVISITN*TRTPN*AGEGRP			>=55	3	2	
AVISITN*TRTPN*AGEGRP			<55	3	3	
AVISITN*TRTPN*AGEGRP			>=55	3	3	
AVISITN*TRTPN*AGEGRP			<55	3	900	

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*AGEGRP			>=55	3	900	
AVISITN*TRTPN*AGEGRP			<55	6	1	
AVISITN*TRTPN*AGEGRP			>=55	6	1	
AVISITN*TRTPN*AGEGRP			<55	6	2	
AVISITN*TRTPN*AGEGRP			>=55	6	2	
AVISITN*TRTPN*AGEGRP			<55	6	3	
AVISITN*TRTPN*AGEGRP			>=55	6	3	
AVISITN*TRTPN*AGEGRP			<55	6	900	
AVISITN*TRTPN*AGEGRP			>=55	6	900	
AVISITN*TRTPN*AGEGRP			<55	10	1	
AVISITN*TRTPN*AGEGRP			>=55	10	1	
AVISITN*TRTPN*AGEGRP			<55	10	2	1
AVISITN*TRTPN*AGEGRP			>=55	10	2	-1
AVISITN*TRTPN*AGEGRP			<55	10	3	
AVISITN*TRTPN*AGEGRP			>=55	10	3	
AVISITN*TRTPN*AGEGRP			<55	10	900	-1
AVISITN*TRTPN*AGEGRP			>=55	10	900	1
AVISITN*TRTPN*AGEGRP			<55	12	1	

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*AGEGRP			>=55	12	1	
AVISITN*TRTPN*AGEGRP			<55	12	2	
AVISITN*TRTPN*AGEGRP			>=55	12	2	
AVISITN*TRTPN*AGEGRP			<55	12	3	
AVISITN*TRTPN*AGEGRP			>=55	12	3	
AVISITN*TRTPN*AGEGRP			<55	12	900	
AVISITN*TRTPN*AGEGRP			>=55	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL	[REDACTED]	N				
COMBFL	[REDACTED]	Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
AGEGRP			<55			
AGEGRP			>=55			
AVISITN*AGEGRP			<55	3		
AVISITN*AGEGRP			>=55	3		
AVISITN*AGEGRP			<55	6		
AVISITN*AGEGRP			>=55	6		
AVISITN*AGEGRP			<55	10		
AVISITN*AGEGRP			>=55	10		
AVISITN*AGEGRP			<55	12		
AVISITN*AGEGRP			>=55	12		
TRTPN*AGEGRP			<55		1	
TRTPN*AGEGRP			>=55		1	
TRTPN*AGEGRP			<55		2	
TRTPN*AGEGRP			>=55		2	
TRTPN*AGEGRP			<55		3	1
TRTPN*AGEGRP			>=55		3	-1
TRTPN*AGEGRP			<55		900	-1

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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*AGEGRP			>=55		900	1
AVISITN*TRTPN*AGEGRP			<55	3	1	
AVISITN*TRTPN*AGEGRP			>=55	3	1	
AVISITN*TRTPN*AGEGRP			<55	3	2	
AVISITN*TRTPN*AGEGRP			>=55	3	2	
AVISITN*TRTPN*AGEGRP			<55	3	3	
AVISITN*TRTPN*AGEGRP			>=55	3	3	
AVISITN*TRTPN*AGEGRP			<55	3	900	
AVISITN*TRTPN*AGEGRP			>=55	3	900	
AVISITN*TRTPN*AGEGRP			<55	6	1	
AVISITN*TRTPN*AGEGRP			>=55	6	1	
AVISITN*TRTPN*AGEGRP			<55	6	2	
AVISITN*TRTPN*AGEGRP			>=55	6	2	
AVISITN*TRTPN*AGEGRP			<55	6	3	
AVISITN*TRTPN*AGEGRP			>=55	6	3	
AVISITN*TRTPN*AGEGRP			<55	6	900	
AVISITN*TRTPN*AGEGRP			>=55	6	900	
AVISITN*TRTPN*AGEGRP			<55	10	1	

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*AGEGRP			>=55	10	1	
AVISITN*TRTPN*AGEGRP			<55	10	2	
AVISITN*TRTPN*AGEGRP			>=55	10	2	
AVISITN*TRTPN*AGEGRP			<55	10	3	1
AVISITN*TRTPN*AGEGRP			>=55	10	3	-1
AVISITN*TRTPN*AGEGRP			<55	10	900	-1
AVISITN*TRTPN*AGEGRP			>=55	10	900	1
AVISITN*TRTPN*AGEGRP			<55	12	1	
AVISITN*TRTPN*AGEGRP			>=55	12	1	
AVISITN*TRTPN*AGEGRP			<55	12	2	
AVISITN*TRTPN*AGEGRP			>=55	12	2	
AVISITN*TRTPN*AGEGRP			<55	12	3	
AVISITN*TRTPN*AGEGRP			>=55	12	3	
AVISITN*TRTPN*AGEGRP			<55	12	900	
AVISITN*TRTPN*AGEGRP			>=55	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.3
MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy W vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]	-2.3988	5.4797	234	-0.44	0.6620
Dummy W vs. Dummy Y BY AGEGRP AT Phase B [REDACTED]	-4.7484	5.8120	225	-0.82	0.4148
Dummy W vs. Dummy X BY AGEGRP AT Phase B [REDACTED]	4.7390	6.3558	238	0.75	0.4566
Dummy X vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]	-7.1378	6.2185	246	-1.15	0.2521
Dummy Y vs. Dummy Z BY AGEGRP AT Phase B [REDACTED]	2.3495	5.6950	233	0.41	0.6803

FILE: stat2c.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-3.3 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Least Squares Means

Effect	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN*AGEGRP	<55	3	1	-6.0540	1.1585	285	-5.23	<.0001	0.05	-8.3343	-3.7738
AVISITN*TRTPN*AGEGRP	>=55	3	1	-9.3081	2.7517	277	-3.38	0.0008	0.05	-14.7250	-3.8912
AVISITN*TRTPN*AGEGRP	<55	3	2	-4.5801	1.2340	285	-3.71	0.0002	0.05	-7.0091	-2.1512
AVISITN*TRTPN*AGEGRP	>=55	3	2	-5.9322	3.3290	290	-1.78	0.0758	0.05	-12.4843	0.6198
AVISITN*TRTPN*AGEGRP	<55	3	3	-6.1834	1.1706	282	-5.28	<.0001	0.05	-8.4876	-3.8792
AVISITN*TRTPN*AGEGRP	>=55	3	3	-6.9955	3.0210	276	-2.32	0.0213	0.05	-12.9426	-1.0484
AVISITN*TRTPN*AGEGRP	<55	3	900	-5.5459	1.1533	281	-4.81	<.0001	0.05	-7.8161	-3.2758
AVISITN*TRTPN*AGEGRP	>=55	3	900	-10.3677	2.6369	277	-3.93	0.0001	0.05	-15.5586	-5.1767
AVISITN*TRTPN*AGEGRP	<55	6	1	-12.4948	1.4252	269	-8.77	<.0001	0.05	-15.3007	-9.6889
AVISITN*TRTPN*AGEGRP	>=55	6	1	-14.0505	3.6151	285	-3.89	0.0001	0.05	-21.1662	-6.9348
AVISITN*TRTPN*AGEGRP	<55	6	2	-8.7265	1.5135	288	-5.77	<.0001	0.05	-11.7055	-5.7476
AVISITN*TRTPN*AGEGRP	>=55	6	2	-2.1002	4.2485	274	-0.49	0.6215	0.05	-10.4640	6.2637
AVISITN*TRTPN*AGEGRP	<55	6	3	-9.3506	1.4610	282	-6.40	<.0001	0.05	-12.2264	-6.4747
AVISITN*TRTPN*AGEGRP	>=55	6	3	-12.8014	3.7811	260	-3.39	0.0008	0.05	-20.2468	-5.3560
AVISITN*TRTPN*AGEGRP	<55	6	900	-8.9035	1.4066	265	-6.33	<.0001	0.05	-11.6731	-6.1339
AVISITN*TRTPN*AGEGRP	>=55	6	900	-9.0182	3.2840	272	-2.75	0.0064	0.05	-15.4835	-2.5530
AVISITN*TRTPN*AGEGRP	<55	10	1	-16.4575	1.5350	244	-10.72	<.0001	0.05	-19.4811	-13.4338
AVISITN*TRTPN*AGEGRP	>=55	10	1	-16.8256	3.7412	232	-4.50	<.0001	0.05	-24.1966	-9.4546
AVISITN*TRTPN*AGEGRP	<55	10	2	-12.6899	1.6539	274	-7.67	<.0001	0.05	-15.9459	-9.4339

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 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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 PROTOCOL 331-201-00061

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STAT-3.3
 MMRM Output for Test on Treatment by Age (<55 vs >=55) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Least Squares Means

Effect	AGEGRP	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN*AGEGRP	>=55	10	2	-8.3190	4.7195	253	-1.76	0.0792	0.05	-17.6136	0.9755
AVISITN*TRTPN*AGEGRP	<55	10	3	-10.7824	1.5611	251	-6.91	<.0001	0.05	-13.8569	-7.7078
AVISITN*TRTPN*AGEGRP	>=55	10	3	-15.8989	3.9845	226	-3.99	<.0001	0.05	-23.7505	-8.0473
AVISITN*TRTPN*AGEGRP	<55	10	900	-10.1139	1.5122	244	-6.69	<.0001	0.05	-13.0926	-7.1352
AVISITN*TRTPN*AGEGRP	>=55	10	900	-12.8809	3.4993	248	-3.68	0.0003	0.05	-19.7729	-5.9889
AVISITN*TRTPN*AGEGRP	<55	12	1	-17.3985	1.6839	252	-10.33	<.0001	0.05	-20.7149	-14.0822
AVISITN*TRTPN*AGEGRP	>=55	12	1	-17.2620	4.0450	234	-4.27	<.0001	0.05	-25.2314	-9.2927
AVISITN*TRTPN*AGEGRP	<55	12	2	-13.0650	1.7885	271	-7.30	<.0001	0.05	-16.5862	-9.5439
AVISITN*TRTPN*AGEGRP	>=55	12	2	-4.7770	5.4143	276	-0.88	0.3784	0.05	-15.4355	5.8815
AVISITN*TRTPN*AGEGRP	<55	12	3	-14.4569	1.6922	254	-8.54	<.0001	0.05	-17.7894	-11.1243
AVISITN*TRTPN*AGEGRP	>=55	12	3	-18.6102	4.3104	228	-4.32	<.0001	0.05	-27.1036	-10.1169
AVISITN*TRTPN*AGEGRP	<55	12	900	-11.2200	1.6606	254	-6.76	<.0001	0.05	-14.4902	-7.9497
AVISITN*TRTPN*AGEGRP	>=55	12	900	-14.5274	3.6625	231	-3.97	<.0001	0.05	-21.7435	-7.3113

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STAT-3.4.1
MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
AVISITN	4	3 6 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	[REDACTED]
COMBFL	2	N Y

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STAT-3.4.1
MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	299	[REDACTED]

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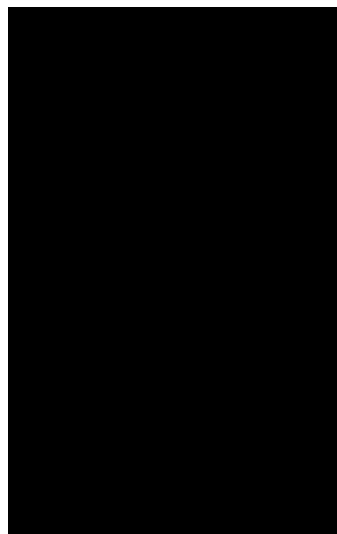
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STAT-3.4.1
MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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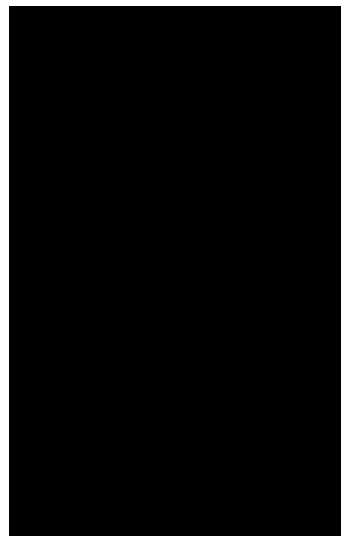
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STAT-3.4.1
MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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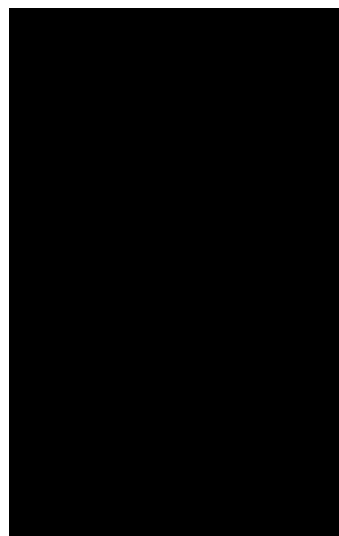
BREXPIRAZOLE
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STAT-3.4.1
MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



FILE: stat2dl.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.4.1
MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

MPLC20FL 2 N Y

Dimensions

Covariance Parameters	10
Columns in X	91
Columns in Z	0
Subjects	299
Max Obs per Subject	4

Number of Observations

Number of Observations Read	996
Number of Observations Used	996
Number of Observations Not Used	0

FILE: stat2dl.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	7332.70126632	
1	2	6866.76001648	0.00042716
2	1	6865.55160256	0.00001410
3	1	6865.51465725	0.00000002
4	1	6865.51460943	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	78.6501
UN(2,1)	SUBJID	52.3865
UN(2,2)	SUBJID	110.71
UN(3,1)	SUBJID	43.4941
UN(3,2)	SUBJID	86.9959
UN(3,3)	SUBJID	122.56
UN(4,1)	SUBJID	49.1894

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STAT-3.4.1
MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,2)	SUBJID	88.8299
UN(4,3)	SUBJID	104.30
UN(4,4)	SUBJID	147.67

Fit Statistics

-2 Res Log Likelihood	6865.5
AIC (Smaller is Better)	6885.5
AICC (Smaller is Better)	6885.7
BIC (Smaller is Better)	6922.5

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
9	467.19	<.0001

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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
POOLCNTR	9	277	1.63	0.1060
COMBFL	1	278	3.21	0.0743
AVISITN	3	227	1.52	0.2098
TRTPN	3	267	2.99	0.0316
AVISITN*TRTPN	9	361	2.04	0.0347
MPLC20FL	1	278	0.00	0.9560
AVISITN*MPLC20FL	3	238	0.71	0.5457
TRTPN*MPLC20FL	3	269	1.83	0.1427
AVISIT*TRTPN*MPLC20F	9	361	1.29	0.2401
BASE*AVISITN	4	240	8.09	<.0001

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STAT-3.4.1
MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		

FILE: stat2dl.iis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	

FILE: stat2dl.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
MPLC20FL			N			
MPLC20FL			Y			
AVISITN*MPLC20FL			N	3		
AVISITN*MPLC20FL			Y	3		
AVISITN*MPLC20FL			N	6		
AVISITN*MPLC20FL			Y	6		
AVISITN*MPLC20FL			N	10		
AVISITN*MPLC20FL			Y	10		
AVISITN*MPLC20FL			N	12		
AVISITN*MPLC20FL			Y	12		
TRTPN*MPLC20FL			N		1	1
TRTPN*MPLC20FL			Y		1	-1
TRTPN*MPLC20FL			N		2	
TRTPN*MPLC20FL			Y		2	

FILE: stat2d1.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.1
 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*MPLC20FL			N		3	
TRTPN*MPLC20FL			Y		3	
TRTPN*MPLC20FL			N		900	-1
TRTPN*MPLC20FL			Y		900	1
AVISIT*TRTPN*MPLC20F			N	3	1	
AVISIT*TRTPN*MPLC20F			Y	3	1	
AVISIT*TRTPN*MPLC20F			N	3	2	
AVISIT*TRTPN*MPLC20F			Y	3	2	
AVISIT*TRTPN*MPLC20F			N	3	3	
AVISIT*TRTPN*MPLC20F			Y	3	3	
AVISIT*TRTPN*MPLC20F			N	3	900	
AVISIT*TRTPN*MPLC20F			Y	3	900	
AVISIT*TRTPN*MPLC20F			N	6	1	
AVISIT*TRTPN*MPLC20F			Y	6	1	
AVISIT*TRTPN*MPLC20F			N	6	2	
AVISIT*TRTPN*MPLC20F			Y	6	2	
AVISIT*TRTPN*MPLC20F			N	6	3	

FILE: stat2dl.iis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-3.4.1 FINAL

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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC20F			Y	6	3	
AVISIT*TRTPN*MPLC20F			N	6	900	
AVISIT*TRTPN*MPLC20F			Y	6	900	
AVISIT*TRTPN*MPLC20F			N	10	1	1
AVISIT*TRTPN*MPLC20F			Y	10	1	-1
AVISIT*TRTPN*MPLC20F			N	10	2	
AVISIT*TRTPN*MPLC20F			Y	10	2	
AVISIT*TRTPN*MPLC20F			N	10	3	
AVISIT*TRTPN*MPLC20F			Y	10	3	
AVISIT*TRTPN*MPLC20F			N	10	900	-1
AVISIT*TRTPN*MPLC20F			Y	10	900	1
AVISIT*TRTPN*MPLC20F			N	12	1	
AVISIT*TRTPN*MPLC20F			Y	12	1	
AVISIT*TRTPN*MPLC20F			N	12	2	
AVISIT*TRTPN*MPLC20F			Y	12	2	
AVISIT*TRTPN*MPLC20F			N	12	3	
AVISIT*TRTPN*MPLC20F			Y	12	3	

FILE: stat2dl.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.4.1
MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC20F			N	12	900	
AVISIT*TRTPN*MPLC20F			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

FILE: stat2dl.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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PROTOCOL 331-201-00061

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STAT-3.4.1
MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		

FILE: stat2dl.iis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	

FILE: stat2dl.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.1
 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
MPLC20FL			N			
MPLC20FL			Y			
AVISITN*MPLC20FL			N	3		
AVISITN*MPLC20FL			Y	3		
AVISITN*MPLC20FL			N	6		
AVISITN*MPLC20FL			Y	6		
AVISITN*MPLC20FL			N	10		
AVISITN*MPLC20FL			Y	10		
AVISITN*MPLC20FL			N	12		
AVISITN*MPLC20FL			Y	12		
TRTPN*MPLC20FL			N		1	1
TRTPN*MPLC20FL			Y		1	-1
TRTPN*MPLC20FL			N		2	
TRTPN*MPLC20FL			Y		2	

FILE: stat2dl.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*MPLC20FL			N		3	-1
TRTPN*MPLC20FL			Y		3	1
TRTPN*MPLC20FL			N		900	
TRTPN*MPLC20FL			Y		900	
AVISIT*TRTPN*MPLC20F			N	3	1	
AVISIT*TRTPN*MPLC20F			Y	3	1	
AVISIT*TRTPN*MPLC20F			N	3	2	
AVISIT*TRTPN*MPLC20F			Y	3	2	
AVISIT*TRTPN*MPLC20F			N	3	3	
AVISIT*TRTPN*MPLC20F			Y	3	3	
AVISIT*TRTPN*MPLC20F			N	3	900	
AVISIT*TRTPN*MPLC20F			Y	3	900	
AVISIT*TRTPN*MPLC20F			N	6	1	
AVISIT*TRTPN*MPLC20F			Y	6	1	
AVISIT*TRTPN*MPLC20F			N	6	2	
AVISIT*TRTPN*MPLC20F			Y	6	2	
AVISIT*TRTPN*MPLC20F			N	6	3	

FILE: stat2dl.iis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC20F			Y	6	3	
AVISIT*TRTPN*MPLC20F			N	6	900	
AVISIT*TRTPN*MPLC20F			Y	6	900	
AVISIT*TRTPN*MPLC20F			N	10	1	1
AVISIT*TRTPN*MPLC20F			Y	10	1	-1
AVISIT*TRTPN*MPLC20F			N	10	2	
AVISIT*TRTPN*MPLC20F			Y	10	2	
AVISIT*TRTPN*MPLC20F			N	10	3	-1
AVISIT*TRTPN*MPLC20F			Y	10	3	1
AVISIT*TRTPN*MPLC20F			N	10	900	
AVISIT*TRTPN*MPLC20F			Y	10	900	
AVISIT*TRTPN*MPLC20F			N	12	1	
AVISIT*TRTPN*MPLC20F			Y	12	1	
AVISIT*TRTPN*MPLC20F			N	12	2	
AVISIT*TRTPN*MPLC20F			Y	12	2	
AVISIT*TRTPN*MPLC20F			N	12	3	
AVISIT*TRTPN*MPLC20F			Y	12	3	

FILE: stat2dl.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.4.1
MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC20F			N	12	900	
AVISIT*TRTPN*MPLC20F			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

FILE: stat2dl.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.4.1
MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL	[REDACTED]	N				
COMBFL	[REDACTED]	Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		

FILE: stat2dl.iis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	

FILE: stat2dl.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
MPLC20FL			N			
MPLC20FL			Y			
AVISITN*MPLC20FL			N	3		
AVISITN*MPLC20FL			Y	3		
AVISITN*MPLC20FL			N	6		
AVISITN*MPLC20FL			Y	6		
AVISITN*MPLC20FL			N	10		
AVISITN*MPLC20FL			Y	10		
AVISITN*MPLC20FL			N	12		
AVISITN*MPLC20FL			Y	12		
TRTPN*MPLC20FL			N		1	1
TRTPN*MPLC20FL			Y		1	-1
TRTPN*MPLC20FL			N		2	-1
TRTPN*MPLC20FL			Y		2	1

FILE: stat2d1.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.1
 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*MPLC20FL			N		3	
TRTPN*MPLC20FL			Y		3	
TRTPN*MPLC20FL			N		900	
TRTPN*MPLC20FL			Y		900	
AVISIT*TRTPN*MPLC20F			N	3	1	
AVISIT*TRTPN*MPLC20F			Y	3	1	
AVISIT*TRTPN*MPLC20F			N	3	2	
AVISIT*TRTPN*MPLC20F			Y	3	2	
AVISIT*TRTPN*MPLC20F			N	3	3	
AVISIT*TRTPN*MPLC20F			Y	3	3	
AVISIT*TRTPN*MPLC20F			N	3	900	
AVISIT*TRTPN*MPLC20F			Y	3	900	
AVISIT*TRTPN*MPLC20F			N	6	1	
AVISIT*TRTPN*MPLC20F			Y	6	1	
AVISIT*TRTPN*MPLC20F			N	6	2	
AVISIT*TRTPN*MPLC20F			Y	6	2	
AVISIT*TRTPN*MPLC20F			N	6	3	

FILE: stat2dl.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC20F			Y	6	3	
AVISIT*TRTPN*MPLC20F			N	6	900	
AVISIT*TRTPN*MPLC20F			Y	6	900	
AVISIT*TRTPN*MPLC20F			N	10	1	1
AVISIT*TRTPN*MPLC20F			Y	10	1	-1
AVISIT*TRTPN*MPLC20F			N	10	2	-1
AVISIT*TRTPN*MPLC20F			Y	10	2	1
AVISIT*TRTPN*MPLC20F			N	10	3	
AVISIT*TRTPN*MPLC20F			Y	10	3	
AVISIT*TRTPN*MPLC20F			N	10	900	
AVISIT*TRTPN*MPLC20F			Y	10	900	
AVISIT*TRTPN*MPLC20F			N	12	1	
AVISIT*TRTPN*MPLC20F			Y	12	1	
AVISIT*TRTPN*MPLC20F			N	12	2	
AVISIT*TRTPN*MPLC20F			Y	12	2	
AVISIT*TRTPN*MPLC20F			N	12	3	
AVISIT*TRTPN*MPLC20F			Y	12	3	

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 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.4.1
MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC20F			N	12	900	
AVISIT*TRTPN*MPLC20F			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.4.1
MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		

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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.1
 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
MPLC20FL			N			
MPLC20FL			Y			
AVISITN*MPLC20FL			N	3		
AVISITN*MPLC20FL			Y	3		
AVISITN*MPLC20FL			N	6		
AVISITN*MPLC20FL			Y	6		
AVISITN*MPLC20FL			N	10		
AVISITN*MPLC20FL			Y	10		
AVISITN*MPLC20FL			N	12		
AVISITN*MPLC20FL			Y	12		
TRTPN*MPLC20FL			N		1	
TRTPN*MPLC20FL			Y		1	
TRTPN*MPLC20FL			N		2	1
TRTPN*MPLC20FL			Y		2	-1

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.1
 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*MPLC20FL			N		3	
TRTPN*MPLC20FL			Y		3	
TRTPN*MPLC20FL			N		900	-1
TRTPN*MPLC20FL			Y		900	1
AVISIT*TRTPN*MPLC20F			N	3	1	
AVISIT*TRTPN*MPLC20F			Y	3	1	
AVISIT*TRTPN*MPLC20F			N	3	2	
AVISIT*TRTPN*MPLC20F			Y	3	2	
AVISIT*TRTPN*MPLC20F			N	3	3	
AVISIT*TRTPN*MPLC20F			Y	3	3	
AVISIT*TRTPN*MPLC20F			N	3	900	
AVISIT*TRTPN*MPLC20F			Y	3	900	
AVISIT*TRTPN*MPLC20F			N	6	1	
AVISIT*TRTPN*MPLC20F			Y	6	1	
AVISIT*TRTPN*MPLC20F			N	6	2	
AVISIT*TRTPN*MPLC20F			Y	6	2	
AVISIT*TRTPN*MPLC20F			N	6	3	

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.1
 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC20F			Y	6	3	
AVISIT*TRTPN*MPLC20F			N	6	900	
AVISIT*TRTPN*MPLC20F			Y	6	900	
AVISIT*TRTPN*MPLC20F			N	10	1	
AVISIT*TRTPN*MPLC20F			Y	10	1	
AVISIT*TRTPN*MPLC20F			N	10	2	1
AVISIT*TRTPN*MPLC20F			Y	10	2	-1
AVISIT*TRTPN*MPLC20F			N	10	3	
AVISIT*TRTPN*MPLC20F			Y	10	3	
AVISIT*TRTPN*MPLC20F			N	10	900	-1
AVISIT*TRTPN*MPLC20F			Y	10	900	1
AVISIT*TRTPN*MPLC20F			N	12	1	
AVISIT*TRTPN*MPLC20F			Y	12	1	
AVISIT*TRTPN*MPLC20F			N	12	2	
AVISIT*TRTPN*MPLC20F			Y	12	2	
AVISIT*TRTPN*MPLC20F			N	12	3	
AVISIT*TRTPN*MPLC20F			Y	12	3	

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.1
20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC20F			N	12	900	
AVISIT*TRTPN*MPLC20F			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.4.1
MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		

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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	

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MMRM Output for Test on Treatment by ██████████ STAT-3.4.1
 20 Percent Improvement Subgroup Interaction ██████████
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MPLC20FL AT Phase B ██████████

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
MPLC20FL			N			
MPLC20FL			Y			
AVISITN*MPLC20FL			N	3		
AVISITN*MPLC20FL			Y	3		
AVISITN*MPLC20FL			N	6		
AVISITN*MPLC20FL			Y	6		
AVISITN*MPLC20FL			N	10		
AVISITN*MPLC20FL			Y	10		
AVISITN*MPLC20FL			N	12		
AVISITN*MPLC20FL			Y	12		
TRTPN*MPLC20FL			N		1	
TRTPN*MPLC20FL			Y		1	
TRTPN*MPLC20FL			N		2	
TRTPN*MPLC20FL			Y		2	

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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*MPLC20FL			N		3	1
TRTPN*MPLC20FL			Y		3	-1
TRTPN*MPLC20FL			N		900	-1
TRTPN*MPLC20FL			Y		900	1
AVISIT*TRTPN*MPLC20F			N	3	1	
AVISIT*TRTPN*MPLC20F			Y	3	1	
AVISIT*TRTPN*MPLC20F			N	3	2	
AVISIT*TRTPN*MPLC20F			Y	3	2	
AVISIT*TRTPN*MPLC20F			N	3	3	
AVISIT*TRTPN*MPLC20F			Y	3	3	
AVISIT*TRTPN*MPLC20F			N	3	900	
AVISIT*TRTPN*MPLC20F			Y	3	900	
AVISIT*TRTPN*MPLC20F			N	6	1	
AVISIT*TRTPN*MPLC20F			Y	6	1	
AVISIT*TRTPN*MPLC20F			N	6	2	
AVISIT*TRTPN*MPLC20F			Y	6	2	
AVISIT*TRTPN*MPLC20F			N	6	3	

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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC20F			Y	6	3	
AVISIT*TRTPN*MPLC20F			N	6	900	
AVISIT*TRTPN*MPLC20F			Y	6	900	
AVISIT*TRTPN*MPLC20F			N	10	1	
AVISIT*TRTPN*MPLC20F			Y	10	1	
AVISIT*TRTPN*MPLC20F			N	10	2	
AVISIT*TRTPN*MPLC20F			Y	10	2	
AVISIT*TRTPN*MPLC20F			N	10	3	1
AVISIT*TRTPN*MPLC20F			Y	10	3	-1
AVISIT*TRTPN*MPLC20F			N	10	900	-1
AVISIT*TRTPN*MPLC20F			Y	10	900	1
AVISIT*TRTPN*MPLC20F			N	12	1	
AVISIT*TRTPN*MPLC20F			Y	12	1	
AVISIT*TRTPN*MPLC20F			N	12	2	
AVISIT*TRTPN*MPLC20F			Y	12	2	
AVISIT*TRTPN*MPLC20F			N	12	3	
AVISIT*TRTPN*MPLC20F			Y	12	3	

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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC20F			N	12	900	
AVISIT*TRTPN*MPLC20F			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy W vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]	2.1822	4.0427	240	0.54	0.5898
Dummy W vs. Dummy Y BY MPLC20FL AT Phase B [REDACTED]	-8.1316	4.1682	240	-1.95	0.0522
Dummy W vs. Dummy X BY MPLC20FL AT Phase B [REDACTED]	-1.5035	4.2322	246	-0.36	0.7227
Dummy X vs. Dummy Z BY MPLC20FL AT Phase B [REDACTED]	3.6857	4.1596	245	0.89	0.3764

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STAT-3.4.1
 MMRM Output for Test on Treatment by 20 Percent Improvement Subgroup Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy Y vs. Dummy Z BY MPLC20FL AT Phase B	10.3139	4.0937	238	2.52	0.0124

Least Squares Means

Effect	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*MPLC20F	N	3	1	-6.5615	1.4085	284	-4.66	<.0001	0.05	-9.3339	-3.7891
AVISIT*TRTPN*MPLC20F	Y	3	1	-6.0037	1.9400	282	-3.09	0.0022	0.05	-9.8224	-2.1849
AVISIT*TRTPN*MPLC20F	N	3	2	-3.4458	1.5811	288	-2.18	0.0301	0.05	-6.5578	-0.3337
AVISIT*TRTPN*MPLC20F	Y	3	2	-6.0500	1.9577	277	-3.09	0.0022	0.05	-9.9037	-2.1962
AVISIT*TRTPN*MPLC20F	N	3	3	-5.1128	1.4555	283	-3.51	0.0005	0.05	-7.9778	-2.2479
AVISIT*TRTPN*MPLC20F	Y	3	3	-7.8652	1.9022	277	-4.13	<.0001	0.05	-11.6099	-4.1205
AVISIT*TRTPN*MPLC20F	N	3	900	-5.7150	1.4184	282	-4.03	<.0001	0.05	-8.5071	-2.9229
AVISIT*TRTPN*MPLC20F	Y	3	900	-6.9412	1.8409	280	-3.77	0.0002	0.05	-10.5650	-3.3173
AVISIT*TRTPN*MPLC20F	N	6	1	-13.5581	1.7282	276	-7.85	<.0001	0.05	-16.9601	-10.1561

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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*MPLC20F	Y	6	1	-10.7737	2.3847	269	-4.52	<.0001	0.05	-15.4687	-6.0787
AVISIT*TRTPN*MPLC20F	N	6	2	-9.0933	1.8693	279	-4.86	<.0001	0.05	-12.7731	-5.4136
AVISIT*TRTPN*MPLC20F	Y	6	2	-5.5330	2.4967	285	-2.22	0.0275	0.05	-10.4474	-0.6187
AVISIT*TRTPN*MPLC20F	N	6	3	-7.8726	1.7683	288	-4.45	<.0001	0.05	-11.3532	-4.3921
AVISIT*TRTPN*MPLC20F	Y	6	3	-13.2503	2.4170	270	-5.48	<.0001	0.05	-18.0088	-8.4919
AVISIT*TRTPN*MPLC20F	N	6	900	-9.9567	1.6917	276	-5.89	<.0001	0.05	-13.2870	-6.6264
AVISIT*TRTPN*MPLC20F	Y	6	900	-6.5873	2.2559	262	-2.92	0.0038	0.05	-11.0294	-2.1452
AVISIT*TRTPN*MPLC20F	N	10	1	-17.0866	1.8532	243	-9.22	<.0001	0.05	-20.7369	-13.4363
AVISIT*TRTPN*MPLC20F	Y	10	1	-15.0059	2.6076	250	-5.75	<.0001	0.05	-20.1416	-9.8701
AVISIT*TRTPN*MPLC20F	N	10	2	-12.3417	2.0363	261	-6.06	<.0001	0.05	-16.3514	-8.3320
AVISIT*TRTPN*MPLC20F	Y	10	2	-11.7644	2.7677	268	-4.25	<.0001	0.05	-17.2137	-6.3152
AVISIT*TRTPN*MPLC20F	N	10	3	-9.3241	1.8849	254	-4.95	<.0001	0.05	-13.0362	-5.6120
AVISIT*TRTPN*MPLC20F	Y	10	3	-15.3750	2.6230	243	-5.86	<.0001	0.05	-20.5417	-10.2083
AVISIT*TRTPN*MPLC20F	N	10	900	-11.8453	1.8076	253	-6.55	<.0001	0.05	-15.4052	-8.2855
AVISIT*TRTPN*MPLC20F	Y	10	900	-7.5823	2.4699	240	-3.07	0.0024	0.05	-12.4477	-2.7169
AVISIT*TRTPN*MPLC20F	N	12	1	-17.2653	2.0451	247	-8.44	<.0001	0.05	-21.2934	-13.2371
AVISIT*TRTPN*MPLC20F	Y	12	1	-17.2662	2.9034	259	-5.95	<.0001	0.05	-22.9835	-11.5490

FILE: stat2d1.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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STAT-3.4.1
 MMRM Output for Test on Treatment by [REDACTED] 20 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	Placebo 20% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*MPLC20F	N	12	2	-13.4015	2.2279	260	-6.02	<.0001	0.05	-17.7885	-9.0146
AVISIT*TRTPN*MPLC20F	Y	12	2	-9.9391	3.0657	267	-3.24	0.0013	0.05	-15.9753	-3.9030
AVISIT*TRTPN*MPLC20F	N	12	3	-13.5215	2.0656	257	-6.55	<.0001	0.05	-17.5892	-9.4537
AVISIT*TRTPN*MPLC20F	Y	12	3	-17.6365	2.8456	237	-6.20	<.0001	0.05	-23.2424	-12.0305
AVISIT*TRTPN*MPLC20F	N	12	900	-12.6255	1.9587	248	-6.45	<.0001	0.05	-16.4833	-8.7677
AVISIT*TRTPN*MPLC20F	Y	12	900	-9.6046	2.8125	259	-3.41	0.0007	0.05	-15.1428	-4.0664

FILE: stat2dl.iis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.4.2
 MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
AVISITN	4	3 6 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	[REDACTED]
COMBFL	2	N Y

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STAT-3.4.2
MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	299	[REDACTED]

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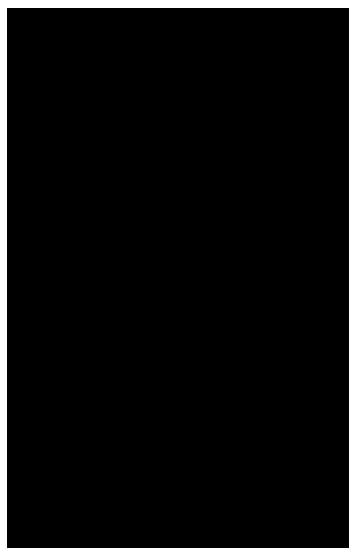
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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.2
25 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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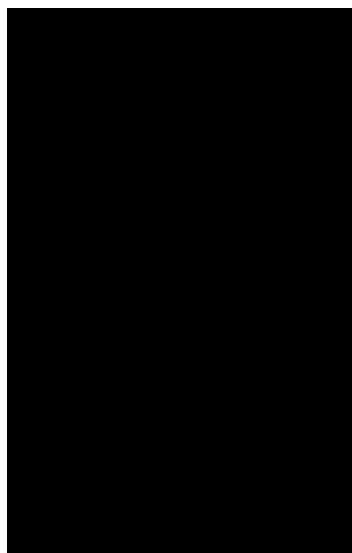
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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.2
25 Percent Improvement Subgroup Interaction [REDACTED]
(to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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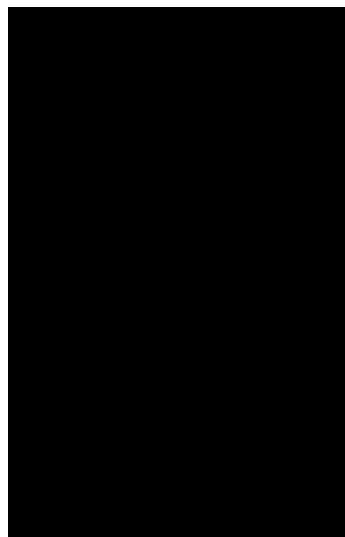
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STAT-3.4.2
MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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STAT-3.4.2
MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

MPLC25FL 2 N Y

Dimensions

Covariance Parameters	10
Columns in X	91
Columns in Z	0
Subjects	299
Max Obs per Subject	4

Number of Observations

Number of Observations Read	996
Number of Observations Used	996
Number of Observations Not Used	0

FILE: stat2d2.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.4.2
 MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	7331.93442443	
1	2	6868.02890783	0.00045719
2	1	6866.73189863	0.00001605
3	1	6866.68977151	0.00000002
4	1	6866.68970952	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	78.4737
UN(2,1)	SUBJID	51.8355
UN(2,2)	SUBJID	111.08
UN(3,1)	SUBJID	43.4739
UN(3,2)	SUBJID	87.8417
UN(3,3)	SUBJID	123.42
UN(4,1)	SUBJID	48.3413

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STAT-3.4.2
MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,2)	SUBJID	88.5051
UN(4,3)	SUBJID	104.04
UN(4,4)	SUBJID	146.60

Fit Statistics

-2 Res Log Likelihood	6866.7
AIC (Smaller is Better)	6886.7
AICC (Smaller is Better)	6886.9
BIC (Smaller is Better)	6923.7

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
9	465.24	<.0001

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STAT-3.4.2
MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
POOLCNTR	9	277	1.61	0.1112
COMBFL	1	278	3.20	0.0746
AVISITN	3	226	1.00	0.3942
TRTPN	3	266	3.14	0.0257
AVISITN*TRTPN	9	360	1.88	0.0541
MPLC25FL	1	272	0.54	0.4642
AVISITN*MPLC25FL	3	236	0.37	0.7716
TRTPN*MPLC25FL	3	267	2.63	0.0509
AVISIT*TRTPN*MPLC25F	9	360	0.93	0.4994
BASE*AVISITN	4	238	5.76	0.0002

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BREXPIRAZOLE
PROTOCOL 331-201-00061

10 OF 42

MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.2
25 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL	[REDACTED]	N				
COMBFL	[REDACTED]	Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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STAT-3.4.2
 MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	

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STAT-3.4.2
 MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
MPLC25FL			N			
MPLC25FL			Y			
AVISITN*MPLC25FL			N	3		
AVISITN*MPLC25FL			Y	3		
AVISITN*MPLC25FL			N	6		
AVISITN*MPLC25FL			Y	6		
AVISITN*MPLC25FL			N	10		
AVISITN*MPLC25FL			Y	10		
AVISITN*MPLC25FL			N	12		
AVISITN*MPLC25FL			Y	12		
TRTPN*MPLC25FL			N		1	1
TRTPN*MPLC25FL			Y		1	-1
TRTPN*MPLC25FL			N		2	
TRTPN*MPLC25FL			Y		2	

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 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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 PROTOCOL 331-201-00061

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STAT-3.4.2
 MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*MPLC25FL			N		3	
TRTPN*MPLC25FL			Y		3	
TRTPN*MPLC25FL			N		900	-1
TRTPN*MPLC25FL			Y		900	1
AVISIT*TRTPN*MPLC25F			N	3	1	
AVISIT*TRTPN*MPLC25F			Y	3	1	
AVISIT*TRTPN*MPLC25F			N	3	2	
AVISIT*TRTPN*MPLC25F			Y	3	2	
AVISIT*TRTPN*MPLC25F			N	3	3	
AVISIT*TRTPN*MPLC25F			Y	3	3	
AVISIT*TRTPN*MPLC25F			N	3	900	
AVISIT*TRTPN*MPLC25F			Y	3	900	
AVISIT*TRTPN*MPLC25F			N	6	1	
AVISIT*TRTPN*MPLC25F			Y	6	1	
AVISIT*TRTPN*MPLC25F			N	6	2	
AVISIT*TRTPN*MPLC25F			Y	6	2	
AVISIT*TRTPN*MPLC25F			N	6	3	

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 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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STAT-3.4.2
 MMRM Output for Test on Treatment by 25 Percent Improvement Subgroup Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MPLC25FL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC25F			Y	6	3	
AVISIT*TRTPN*MPLC25F			N	6	900	
AVISIT*TRTPN*MPLC25F			Y	6	900	
AVISIT*TRTPN*MPLC25F			N	10	1	1
AVISIT*TRTPN*MPLC25F			Y	10	1	-1
AVISIT*TRTPN*MPLC25F			N	10	2	
AVISIT*TRTPN*MPLC25F			Y	10	2	
AVISIT*TRTPN*MPLC25F			N	10	3	
AVISIT*TRTPN*MPLC25F			Y	10	3	
AVISIT*TRTPN*MPLC25F			N	10	900	-1
AVISIT*TRTPN*MPLC25F			Y	10	900	1
AVISIT*TRTPN*MPLC25F			N	12	1	
AVISIT*TRTPN*MPLC25F			Y	12	1	
AVISIT*TRTPN*MPLC25F			N	12	2	
AVISIT*TRTPN*MPLC25F			Y	12	2	
AVISIT*TRTPN*MPLC25F			N	12	3	
AVISIT*TRTPN*MPLC25F			Y	12	3	

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.2
25 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC25F			N	12	900	
AVISIT*TRTPN*MPLC25F			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.4.2
MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		

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STAT-3.4.2
 MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	

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STAT-3.4.2
 MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
MPLC25FL			N			
MPLC25FL			Y			
AVISITN*MPLC25FL			N	3		
AVISITN*MPLC25FL			Y	3		
AVISITN*MPLC25FL			N	6		
AVISITN*MPLC25FL			Y	6		
AVISITN*MPLC25FL			N	10		
AVISITN*MPLC25FL			Y	10		
AVISITN*MPLC25FL			N	12		
AVISITN*MPLC25FL			Y	12		
TRTPN*MPLC25FL			N		1	1
TRTPN*MPLC25FL			Y		1	-1
TRTPN*MPLC25FL			N		2	
TRTPN*MPLC25FL			Y		2	

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STAT-3.4.2
 MMRM Output for Test on Treatment by 25 Percent Improvement Subgroup Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MPLC25FL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*MPLC25FL			N		3	-1
TRTPN*MPLC25FL			Y		3	1
TRTPN*MPLC25FL			N		900	
TRTPN*MPLC25FL			Y		900	
AVISIT*TRTPN*MPLC25F			N	3	1	
AVISIT*TRTPN*MPLC25F			Y	3	1	
AVISIT*TRTPN*MPLC25F			N	3	2	
AVISIT*TRTPN*MPLC25F			Y	3	2	
AVISIT*TRTPN*MPLC25F			N	3	3	
AVISIT*TRTPN*MPLC25F			Y	3	3	
AVISIT*TRTPN*MPLC25F			N	3	900	
AVISIT*TRTPN*MPLC25F			Y	3	900	
AVISIT*TRTPN*MPLC25F			N	6	1	
AVISIT*TRTPN*MPLC25F			Y	6	1	
AVISIT*TRTPN*MPLC25F			N	6	2	
AVISIT*TRTPN*MPLC25F			Y	6	2	
AVISIT*TRTPN*MPLC25F			N	6	3	

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STAT-3.4.2
MMRM Output for Test on Treatment by 25 Percent Improvement Subgroup Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MPLC25FL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC25F			Y	6	3	
AVISIT*TRTPN*MPLC25F			N	6	900	
AVISIT*TRTPN*MPLC25F			Y	6	900	
AVISIT*TRTPN*MPLC25F			N	10	1	1
AVISIT*TRTPN*MPLC25F			Y	10	1	-1
AVISIT*TRTPN*MPLC25F			N	10	2	
AVISIT*TRTPN*MPLC25F			Y	10	2	
AVISIT*TRTPN*MPLC25F			N	10	3	-1
AVISIT*TRTPN*MPLC25F			Y	10	3	1
AVISIT*TRTPN*MPLC25F			N	10	900	
AVISIT*TRTPN*MPLC25F			Y	10	900	
AVISIT*TRTPN*MPLC25F			N	12	1	
AVISIT*TRTPN*MPLC25F			Y	12	1	
AVISIT*TRTPN*MPLC25F			N	12	2	
AVISIT*TRTPN*MPLC25F			Y	12	2	
AVISIT*TRTPN*MPLC25F			N	12	3	
AVISIT*TRTPN*MPLC25F			Y	12	3	

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STAT-3.4.2
MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC25F			N	12	900	
AVISIT*TRTPN*MPLC25F			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.4.2
MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNR	[REDACTED]					
POOLCNR	[REDACTED]					
POOLCNR	[REDACTED]					
POOLCNR	[REDACTED]					
POOLCNR	[REDACTED]					
POOLCNR	[REDACTED]					
POOLCNR	[REDACTED]					
POOLCNR	[REDACTED]					
POOLCNR	[REDACTED]					
POOLCNR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.2
 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	

FILE: stat2d2.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.2
 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
MPLC25FL			N			
MPLC25FL			Y			
AVISITN*MPLC25FL			N	3		
AVISITN*MPLC25FL			Y	3		
AVISITN*MPLC25FL			N	6		
AVISITN*MPLC25FL			Y	6		
AVISITN*MPLC25FL			N	10		
AVISITN*MPLC25FL			Y	10		
AVISITN*MPLC25FL			N	12		
AVISITN*MPLC25FL			Y	12		
TRTPN*MPLC25FL			N		1	1
TRTPN*MPLC25FL			Y		1	-1
TRTPN*MPLC25FL			N		2	-1
TRTPN*MPLC25FL			Y		2	1

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STAT-3.4.2
MMRM Output for Test on Treatment by 25 Percent Improvement Subgroup Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MPLC25FL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*MPLC25FL			N		3	
TRTPN*MPLC25FL			Y		3	
TRTPN*MPLC25FL			N		900	
TRTPN*MPLC25FL			Y		900	
AVISIT*TRTPN*MPLC25F			N	3	1	
AVISIT*TRTPN*MPLC25F			Y	3	1	
AVISIT*TRTPN*MPLC25F			N	3	2	
AVISIT*TRTPN*MPLC25F			Y	3	2	
AVISIT*TRTPN*MPLC25F			N	3	3	
AVISIT*TRTPN*MPLC25F			Y	3	3	
AVISIT*TRTPN*MPLC25F			N	3	900	
AVISIT*TRTPN*MPLC25F			Y	3	900	
AVISIT*TRTPN*MPLC25F			N	6	1	
AVISIT*TRTPN*MPLC25F			Y	6	1	
AVISIT*TRTPN*MPLC25F			N	6	2	
AVISIT*TRTPN*MPLC25F			Y	6	2	
AVISIT*TRTPN*MPLC25F			N	6	3	

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STAT-3.4.2
 MMRM Output for Test on Treatment by 25 Percent Improvement Subgroup Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MPLC25FL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC25F			Y	6	3	
AVISIT*TRTPN*MPLC25F			N	6	900	
AVISIT*TRTPN*MPLC25F			Y	6	900	
AVISIT*TRTPN*MPLC25F			N	10	1	1
AVISIT*TRTPN*MPLC25F			Y	10	1	-1
AVISIT*TRTPN*MPLC25F			N	10	2	-1
AVISIT*TRTPN*MPLC25F			Y	10	2	1
AVISIT*TRTPN*MPLC25F			N	10	3	
AVISIT*TRTPN*MPLC25F			Y	10	3	
AVISIT*TRTPN*MPLC25F			N	10	900	
AVISIT*TRTPN*MPLC25F			Y	10	900	
AVISIT*TRTPN*MPLC25F			N	12	1	
AVISIT*TRTPN*MPLC25F			Y	12	1	
AVISIT*TRTPN*MPLC25F			N	12	2	
AVISIT*TRTPN*MPLC25F			Y	12	2	
AVISIT*TRTPN*MPLC25F			N	12	3	
AVISIT*TRTPN*MPLC25F			Y	12	3	

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STAT-3.4.2
 MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC25F			N	12	900	
AVISIT*TRTPN*MPLC25F			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.4.2
MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		

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STAT-3.4.2
 MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	

FILE: stat2d2.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.4.2
 MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
MPLC25FL			N			
MPLC25FL			Y			
AVISITN*MPLC25FL			N	3		
AVISITN*MPLC25FL			Y	3		
AVISITN*MPLC25FL			N	6		
AVISITN*MPLC25FL			Y	6		
AVISITN*MPLC25FL			N	10		
AVISITN*MPLC25FL			Y	10		
AVISITN*MPLC25FL			N	12		
AVISITN*MPLC25FL			Y	12		
TRTPN*MPLC25FL			N		1	
TRTPN*MPLC25FL			Y		1	
TRTPN*MPLC25FL			N		2	1
TRTPN*MPLC25FL			Y		2	-1

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.2
 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*MPLC25FL			N		3	
TRTPN*MPLC25FL			Y		3	
TRTPN*MPLC25FL			N		900	-1
TRTPN*MPLC25FL			Y		900	1
AVISIT*TRTPN*MPLC25F			N	3	1	
AVISIT*TRTPN*MPLC25F			Y	3	1	
AVISIT*TRTPN*MPLC25F			N	3	2	
AVISIT*TRTPN*MPLC25F			Y	3	2	
AVISIT*TRTPN*MPLC25F			N	3	3	
AVISIT*TRTPN*MPLC25F			Y	3	3	
AVISIT*TRTPN*MPLC25F			N	3	900	
AVISIT*TRTPN*MPLC25F			Y	3	900	
AVISIT*TRTPN*MPLC25F			N	6	1	
AVISIT*TRTPN*MPLC25F			Y	6	1	
AVISIT*TRTPN*MPLC25F			N	6	2	
AVISIT*TRTPN*MPLC25F			Y	6	2	
AVISIT*TRTPN*MPLC25F			N	6	3	

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STAT-3.4.2
MMRM Output for Test on Treatment by 25 Percent Improvement Subgroup Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MPLC25FL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC25F			Y	6	3	
AVISIT*TRTPN*MPLC25F			N	6	900	
AVISIT*TRTPN*MPLC25F			Y	6	900	
AVISIT*TRTPN*MPLC25F			N	10	1	
AVISIT*TRTPN*MPLC25F			Y	10	1	
AVISIT*TRTPN*MPLC25F			N	10	2	1
AVISIT*TRTPN*MPLC25F			Y	10	2	-1
AVISIT*TRTPN*MPLC25F			N	10	3	
AVISIT*TRTPN*MPLC25F			Y	10	3	
AVISIT*TRTPN*MPLC25F			N	10	900	-1
AVISIT*TRTPN*MPLC25F			Y	10	900	1
AVISIT*TRTPN*MPLC25F			N	12	1	
AVISIT*TRTPN*MPLC25F			Y	12	1	
AVISIT*TRTPN*MPLC25F			N	12	2	
AVISIT*TRTPN*MPLC25F			Y	12	2	
AVISIT*TRTPN*MPLC25F			N	12	3	
AVISIT*TRTPN*MPLC25F			Y	12	3	

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STAT-3.4.2
MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC25F			N	12	900	
AVISIT*TRTPN*MPLC25F			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.4.2
MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		

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STAT-3.4.2
 MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.2
 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
MPLC25FL			N			
MPLC25FL			Y			
AVISITN*MPLC25FL			N	3		
AVISITN*MPLC25FL			Y	3		
AVISITN*MPLC25FL			N	6		
AVISITN*MPLC25FL			Y	6		
AVISITN*MPLC25FL			N	10		
AVISITN*MPLC25FL			Y	10		
AVISITN*MPLC25FL			N	12		
AVISITN*MPLC25FL			Y	12		
TRTPN*MPLC25FL			N		1	
TRTPN*MPLC25FL			Y		1	
TRTPN*MPLC25FL			N		2	
TRTPN*MPLC25FL			Y		2	

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STAT-3.4.2
 MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*MPLC25FL			N		3	1
TRTPN*MPLC25FL			Y		3	-1
TRTPN*MPLC25FL			N		900	-1
TRTPN*MPLC25FL			Y		900	1
AVISIT*TRTPN*MPLC25F			N	3	1	
AVISIT*TRTPN*MPLC25F			Y	3	1	
AVISIT*TRTPN*MPLC25F			N	3	2	
AVISIT*TRTPN*MPLC25F			Y	3	2	
AVISIT*TRTPN*MPLC25F			N	3	3	
AVISIT*TRTPN*MPLC25F			Y	3	3	
AVISIT*TRTPN*MPLC25F			N	3	900	
AVISIT*TRTPN*MPLC25F			Y	3	900	
AVISIT*TRTPN*MPLC25F			N	6	1	
AVISIT*TRTPN*MPLC25F			Y	6	1	
AVISIT*TRTPN*MPLC25F			N	6	2	
AVISIT*TRTPN*MPLC25F			Y	6	2	
AVISIT*TRTPN*MPLC25F			N	6	3	

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STAT-3.4.2
 MMRM Output for Test on Treatment by 25 Percent Improvement Subgroup Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MPLC25FL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC25F			Y	6	3	
AVISIT*TRTPN*MPLC25F			N	6	900	
AVISIT*TRTPN*MPLC25F			Y	6	900	
AVISIT*TRTPN*MPLC25F			N	10	1	
AVISIT*TRTPN*MPLC25F			Y	10	1	
AVISIT*TRTPN*MPLC25F			N	10	2	
AVISIT*TRTPN*MPLC25F			Y	10	2	
AVISIT*TRTPN*MPLC25F			N	10	3	1
AVISIT*TRTPN*MPLC25F			Y	10	3	-1
AVISIT*TRTPN*MPLC25F			N	10	900	-1
AVISIT*TRTPN*MPLC25F			Y	10	900	1
AVISIT*TRTPN*MPLC25F			N	12	1	
AVISIT*TRTPN*MPLC25F			Y	12	1	
AVISIT*TRTPN*MPLC25F			N	12	2	
AVISIT*TRTPN*MPLC25F			Y	12	2	
AVISIT*TRTPN*MPLC25F			N	12	3	
AVISIT*TRTPN*MPLC25F			Y	12	3	

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STAT-3.4.2
 MMRM Output for Test on Treatment by [REDACTED] 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*MPLC25F			N	12	900	
AVISIT*TRTPN*MPLC25F			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy W vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]	2.3911	4.2234	237	0.57	0.5718
Dummy W vs. Dummy Y BY MPLC25FL AT Phase B [REDACTED]	-8.4054	4.3222	241	-1.94	0.0530
Dummy W vs. Dummy X BY MPLC25FL AT Phase B [REDACTED]	1.7679	4.4392	247	0.40	0.6908
Dummy X vs. Dummy Z BY MPLC25FL AT Phase B [REDACTED]	0.6233	4.3236	242	0.14	0.8855

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STAT-3.4.2
 MMRM Output for Test on Treatment by 25 Percent Improvement Subgroup Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy Y vs. Dummy Z BY MPLC25FL AT Phase B	10.7966	4.1852	236	2.58	0.0105

Least Squares Means

Effect	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*MPLC25F	N	3	1	-7.2255	1.3324	283	-5.42	<.0001	0.05	-9.8481	-4.6029
AVISIT*TRTPN*MPLC25F	Y	3	1	-4.4651	2.1735	281	-2.05	0.0409	0.05	-8.7434	-0.1868
AVISIT*TRTPN*MPLC25F	N	3	2	-4.6549	1.5127	287	-3.08	0.0023	0.05	-7.6324	-1.6775
AVISIT*TRTPN*MPLC25F	Y	3	2	-4.0945	2.1624	277	-1.89	0.0593	0.05	-8.3514	0.1623
AVISIT*TRTPN*MPLC25F	N	3	3	-5.6543	1.4457	283	-3.91	0.0001	0.05	-8.4999	-2.8088
AVISIT*TRTPN*MPLC25F	Y	3	3	-7.3251	1.9363	275	-3.78	0.0002	0.05	-11.1369	-3.5133
AVISIT*TRTPN*MPLC25F	N	3	900	-6.8317	1.3494	282	-5.06	<.0001	0.05	-9.4879	-4.1755
AVISIT*TRTPN*MPLC25F	Y	3	900	-4.7339	2.0506	280	-2.31	0.0217	0.05	-8.7705	-0.6974
AVISIT*TRTPN*MPLC25F	N	6	1	-13.8787	1.6391	273	-8.47	<.0001	0.05	-17.1056	-10.6518

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.2
 25 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*MPLC25F	Y	6	1	-9.5963	2.6507	263	-3.62	0.0004	0.05	-14.8156	-4.3770
AVISIT*TRTPN*MPLC25F	N	6	2	-9.5472	1.7916	280	-5.33	<.0001	0.05	-13.0740	-6.0205
AVISIT*TRTPN*MPLC25F	Y	6	2	-4.1451	2.7626	282	-1.50	0.1346	0.05	-9.5831	1.2928
AVISIT*TRTPN*MPLC25F	N	6	3	-8.2811	1.7534	285	-4.72	<.0001	0.05	-11.7324	-4.8298
AVISIT*TRTPN*MPLC25F	Y	6	3	-12.9846	2.4771	266	-5.24	<.0001	0.05	-17.8618	-8.1074
AVISIT*TRTPN*MPLC25F	N	6	900	-10.0084	1.6245	276	-6.16	<.0001	0.05	-13.2064	-6.8103
AVISIT*TRTPN*MPLC25F	Y	6	900	-6.1814	2.4363	250	-2.54	0.0118	0.05	-10.9797	-1.3831
AVISIT*TRTPN*MPLC25F	N	10	1	-16.9313	1.7597	241	-9.62	<.0001	0.05	-20.3976	-13.4651
AVISIT*TRTPN*MPLC25F	Y	10	1	-15.2122	2.9293	250	-5.19	<.0001	0.05	-20.9814	-9.4431
AVISIT*TRTPN*MPLC25F	N	10	2	-13.2205	1.9706	269	-6.71	<.0001	0.05	-17.1004	-9.3407
AVISIT*TRTPN*MPLC25F	Y	10	2	-9.7336	3.0571	262	-3.18	0.0016	0.05	-15.7532	-3.7140
AVISIT*TRTPN*MPLC25F	N	10	3	-9.2971	1.8724	253	-4.97	<.0001	0.05	-12.9846	-5.6097
AVISIT*TRTPN*MPLC25F	Y	10	3	-15.9835	2.7007	241	-5.92	<.0001	0.05	-21.3036	-10.6633
AVISIT*TRTPN*MPLC25F	N	10	900	-11.6997	1.7509	256	-6.68	<.0001	0.05	-15.1477	-8.2516
AVISIT*TRTPN*MPLC25F	Y	10	900	-7.5894	2.6480	233	-2.87	0.0045	0.05	-12.8065	-2.3724
AVISIT*TRTPN*MPLC25F	N	12	1	-17.5147	1.9377	248	-9.04	<.0001	0.05	-21.3313	-13.6982
AVISIT*TRTPN*MPLC25F	Y	12	1	-16.8118	3.2050	252	-5.25	<.0001	0.05	-23.1239	-10.4998

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STAT-3.4.2
 MMRM Output for Test on Treatment by 25 Percent Improvement Subgroup Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	Placebo 25% Responder Population Flag in	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*MPLC25F	N	12	2	-14.0994	2.1461	268	-6.57	<.0001	0.05	-18.3247	-9.8741
AVISIT*TRTPN*MPLC25F	Y	12	2	-7.8705	3.3613	261	-2.34	0.0200	0.05	-14.4891	-1.2519
AVISIT*TRTPN*MPLC25F	N	12	3	-13.5835	2.0386	256	-6.66	<.0001	0.05	-17.5981	-9.5690
AVISIT*TRTPN*MPLC25F	Y	12	3	-17.9995	2.9117	235	-6.18	<.0001	0.05	-23.7359	-12.2631
AVISIT*TRTPN*MPLC25F	N	12	900	-12.8520	1.8880	252	-6.81	<.0001	0.05	-16.5704	-9.1336
AVISIT*TRTPN*MPLC25F	Y	12	900	-8.8701	3.0061	254	-2.95	0.0035	0.05	-14.7901	-2.9501

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STAT-3.4.3
MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
AVISITN	4	3 6 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	[REDACTED]
COMBFL	2	N Y

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STAT-3.4.3
MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	299	[REDACTED]

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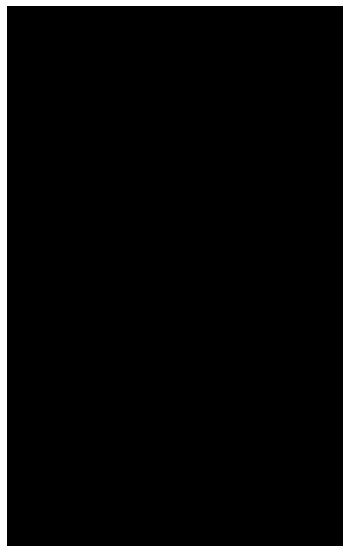
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STAT-3.4.3
MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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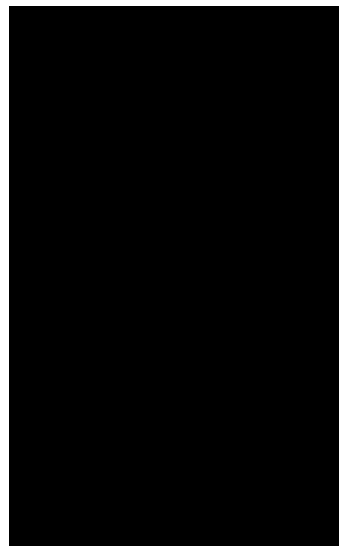
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STAT-3.4.3
MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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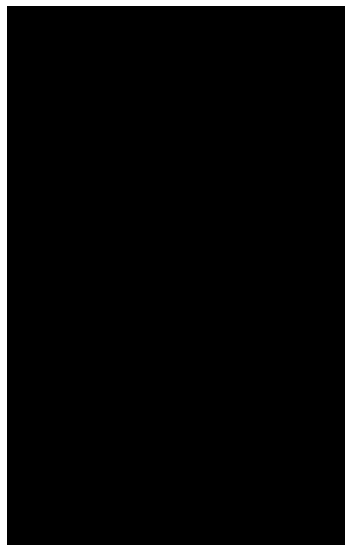
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STAT-3.4.3
MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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STAT-3.4.3
MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

MITTFL 2 N Y

Dimensions

Covariance Parameters	10
Columns in X	91
Columns in Z	0
Subjects	299
Max Obs per Subject	4

Number of Observations

Number of Observations Read	996
Number of Observations Used	996
Number of Observations Not Used	0

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.3
30 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	7337.68028425	
1	2	6868.62941909	0.00042848
2	1	6867.41753019	0.00001401
3	1	6867.38081232	0.00000002
4	1	6867.38076515	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	77.6215
UN(2,1)	SUBJID	51.7432
UN(2,2)	SUBJID	112.81
UN(3,1)	SUBJID	42.7606
UN(3,2)	SUBJID	88.8408
UN(3,3)	SUBJID	124.03
UN(4,1)	SUBJID	47.7890

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.3
30 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,2)	SUBJID	89.4074
UN(4,3)	SUBJID	104.80
UN(4,4)	SUBJID	147.63

Fit Statistics

-2 Res Log Likelihood	6867.4
AIC (Smaller is Better)	6887.4
AICC (Smaller is Better)	6887.6
BIC (Smaller is Better)	6924.4

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
9	470.30	<.0001

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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
POOLCNTR	9	278	1.71	0.0869
COMBFL	1	279	3.56	0.0601
AVISITN	3	227	0.97	0.4081
TRTPN	3	272	3.79	0.0109
AVISITN*TRTPN	9	360	1.60	0.1130
MITTFL	1	273	0.00	0.9968
AVISITN*MITTFL	3	237	0.18	0.9112
TRTPN*MITTFL	3	273	2.41	0.0674
AVISITN*TRTPN*MITTFL	9	360	0.34	0.9629
BASE*AVISITN	4	240	6.54	<.0001

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STAT-3.4.3
MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.3
 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
MITTFL			N			
MITTFL			Y			
AVISITN*MITTFL			N	3		
AVISITN*MITTFL			Y	3		
AVISITN*MITTFL			N	6		
AVISITN*MITTFL			Y	6		
AVISITN*MITTFL			N	10		
AVISITN*MITTFL			Y	10		
AVISITN*MITTFL			N	12		
AVISITN*MITTFL			Y	12		
TRTPN*MITTFL			N		1	1
TRTPN*MITTFL			Y		1	-1
TRTPN*MITTFL			N		2	
TRTPN*MITTFL			Y		2	
TRTPN*MITTFL			N		3	
TRTPN*MITTFL			Y		3	
TRTPN*MITTFL			N		900	-1

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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*MITTFL			Y		900	1
AVISITN*TRTPN*MITTFL			N	3	1	
AVISITN*TRTPN*MITTFL			Y	3	1	
AVISITN*TRTPN*MITTFL			N	3	2	
AVISITN*TRTPN*MITTFL			Y	3	2	
AVISITN*TRTPN*MITTFL			N	3	3	
AVISITN*TRTPN*MITTFL			Y	3	3	
AVISITN*TRTPN*MITTFL			N	3	900	
AVISITN*TRTPN*MITTFL			Y	3	900	
AVISITN*TRTPN*MITTFL			N	6	1	
AVISITN*TRTPN*MITTFL			Y	6	1	
AVISITN*TRTPN*MITTFL			N	6	2	
AVISITN*TRTPN*MITTFL			Y	6	2	
AVISITN*TRTPN*MITTFL			N	6	3	
AVISITN*TRTPN*MITTFL			Y	6	3	
AVISITN*TRTPN*MITTFL			N	6	900	
AVISITN*TRTPN*MITTFL			Y	6	900	
AVISITN*TRTPN*MITTFL			N	10	1	1

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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*MITTFL			Y	10	1	-1
AVISITN*TRTPN*MITTFL			N	10	2	
AVISITN*TRTPN*MITTFL			Y	10	2	
AVISITN*TRTPN*MITTFL			N	10	3	
AVISITN*TRTPN*MITTFL			Y	10	3	
AVISITN*TRTPN*MITTFL			N	10	900	-1
AVISITN*TRTPN*MITTFL			Y	10	900	1
AVISITN*TRTPN*MITTFL			N	12	1	
AVISITN*TRTPN*MITTFL			Y	12	1	
AVISITN*TRTPN*MITTFL			N	12	2	
AVISITN*TRTPN*MITTFL			Y	12	2	
AVISITN*TRTPN*MITTFL			N	12	3	
AVISITN*TRTPN*MITTFL			Y	12	3	
AVISITN*TRTPN*MITTFL			N	12	900	
AVISITN*TRTPN*MITTFL			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.3
30 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Coefficients for Dummy W vs. Dummy Y BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						

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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	

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STAT-3.4.3
 MMRM Output for Test on Treatment by 30 Percent Improvement Subgroup Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MITTFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
MITTFL			N			
MITTFL			Y			
AVISITN*MITTFL			N	3		
AVISITN*MITTFL			Y	3		
AVISITN*MITTFL			N	6		
AVISITN*MITTFL			Y	6		
AVISITN*MITTFL			N	10		

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 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*MITTFL			Y	10		
AVISITN*MITTFL			N	12		
AVISITN*MITTFL			Y	12		
TRTPN*MITTFL			N		1	1
TRTPN*MITTFL			Y		1	-1
TRTPN*MITTFL			N		2	
TRTPN*MITTFL			Y		2	
TRTPN*MITTFL			N		3	-1
TRTPN*MITTFL			Y		3	1
TRTPN*MITTFL			N		900	
TRTPN*MITTFL			Y		900	
AVISITN*TRTPN*MITTFL			N	3	1	
AVISITN*TRTPN*MITTFL			Y	3	1	
AVISITN*TRTPN*MITTFL			N	3	2	
AVISITN*TRTPN*MITTFL			Y	3	2	
AVISITN*TRTPN*MITTFL			N	3	3	
AVISITN*TRTPN*MITTFL			Y	3	3	
AVISITN*TRTPN*MITTFL			N	3	900	

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 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*MITTFL			Y	3	900	
AVISITN*TRTPN*MITTFL			N	6	1	
AVISITN*TRTPN*MITTFL			Y	6	1	
AVISITN*TRTPN*MITTFL			N	6	2	
AVISITN*TRTPN*MITTFL			Y	6	2	
AVISITN*TRTPN*MITTFL			N	6	3	
AVISITN*TRTPN*MITTFL			Y	6	3	
AVISITN*TRTPN*MITTFL			N	6	900	
AVISITN*TRTPN*MITTFL			Y	6	900	
AVISITN*TRTPN*MITTFL			N	10	1	1
AVISITN*TRTPN*MITTFL			Y	10	1	-1
AVISITN*TRTPN*MITTFL			N	10	2	
AVISITN*TRTPN*MITTFL			Y	10	2	
AVISITN*TRTPN*MITTFL			N	10	3	-1
AVISITN*TRTPN*MITTFL			Y	10	3	1
AVISITN*TRTPN*MITTFL			N	10	900	
AVISITN*TRTPN*MITTFL			Y	10	900	
AVISITN*TRTPN*MITTFL			N	12	1	

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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*MITTFL			Y	12	1	
AVISITN*TRTPN*MITTFL			N	12	2	
AVISITN*TRTPN*MITTFL			Y	12	2	
AVISITN*TRTPN*MITTFL			N	12	3	
AVISITN*TRTPN*MITTFL			Y	12	3	
AVISITN*TRTPN*MITTFL			N	12	900	
AVISITN*TRTPN*MITTFL			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.4.3
MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
MITTFL			N			
MITTFL			Y			
AVISITN*MITTFL			N	3		
AVISITN*MITTFL			Y	3		
AVISITN*MITTFL			N	6		
AVISITN*MITTFL			Y	6		
AVISITN*MITTFL			N	10		
AVISITN*MITTFL			Y	10		
AVISITN*MITTFL			N	12		
AVISITN*MITTFL			Y	12		
TRTPN*MITTFL			N		1	1
TRTPN*MITTFL			Y		1	-1
TRTPN*MITTFL			N		2	-1
TRTPN*MITTFL			Y		2	1
TRTPN*MITTFL			N		3	
TRTPN*MITTFL			Y		3	
TRTPN*MITTFL			N		900	

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.3
 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*MITTFL			Y		900	
AVISITN*TRTPN*MITTFL			N	3	1	
AVISITN*TRTPN*MITTFL			Y	3	1	
AVISITN*TRTPN*MITTFL			N	3	2	
AVISITN*TRTPN*MITTFL			Y	3	2	
AVISITN*TRTPN*MITTFL			N	3	3	
AVISITN*TRTPN*MITTFL			Y	3	3	
AVISITN*TRTPN*MITTFL			N	3	900	
AVISITN*TRTPN*MITTFL			Y	3	900	
AVISITN*TRTPN*MITTFL			N	6	1	
AVISITN*TRTPN*MITTFL			Y	6	1	
AVISITN*TRTPN*MITTFL			N	6	2	
AVISITN*TRTPN*MITTFL			Y	6	2	
AVISITN*TRTPN*MITTFL			N	6	3	
AVISITN*TRTPN*MITTFL			Y	6	3	
AVISITN*TRTPN*MITTFL			N	6	900	
AVISITN*TRTPN*MITTFL			Y	6	900	
AVISITN*TRTPN*MITTFL			N	10	1	1

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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*MITTFL			Y	10	1	-1
AVISITN*TRTPN*MITTFL			N	10	2	-1
AVISITN*TRTPN*MITTFL			Y	10	2	1
AVISITN*TRTPN*MITTFL			N	10	3	
AVISITN*TRTPN*MITTFL			Y	10	3	
AVISITN*TRTPN*MITTFL			N	10	900	
AVISITN*TRTPN*MITTFL			Y	10	900	
AVISITN*TRTPN*MITTFL			N	12	1	
AVISITN*TRTPN*MITTFL			Y	12	1	
AVISITN*TRTPN*MITTFL			N	12	2	
AVISITN*TRTPN*MITTFL			Y	12	2	
AVISITN*TRTPN*MITTFL			N	12	3	
AVISITN*TRTPN*MITTFL			Y	12	3	
AVISITN*TRTPN*MITTFL			N	12	900	
AVISITN*TRTPN*MITTFL			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.4.3
MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Coefficients for Dummy X vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.3
 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	

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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
MITTFL			N			
MITTFL			Y			
AVISITN*MITTFL			N	3		
AVISITN*MITTFL			Y	3		
AVISITN*MITTFL			N	6		
AVISITN*MITTFL			Y	6		
AVISITN*MITTFL			N	10		

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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*MITTFL			Y	10		
AVISITN*MITTFL			N	12		
AVISITN*MITTFL			Y	12		
TRTPN*MITTFL			N		1	
TRTPN*MITTFL			Y		1	
TRTPN*MITTFL			N		2	1
TRTPN*MITTFL			Y		2	-1
TRTPN*MITTFL			N		3	
TRTPN*MITTFL			Y		3	
TRTPN*MITTFL			N		900	-1
TRTPN*MITTFL			Y		900	1
AVISITN*TRTPN*MITTFL			N	3	1	
AVISITN*TRTPN*MITTFL			Y	3	1	
AVISITN*TRTPN*MITTFL			N	3	2	
AVISITN*TRTPN*MITTFL			Y	3	2	
AVISITN*TRTPN*MITTFL			N	3	3	
AVISITN*TRTPN*MITTFL			Y	3	3	
AVISITN*TRTPN*MITTFL			N	3	900	

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STAT-3.4.3
 MMRM Output for Test on Treatment by 30 Percent Improvement Subgroup Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MITTFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*MITTFL			Y	3	900	
AVISITN*TRTPN*MITTFL			N	6	1	
AVISITN*TRTPN*MITTFL			Y	6	1	
AVISITN*TRTPN*MITTFL			N	6	2	
AVISITN*TRTPN*MITTFL			Y	6	2	
AVISITN*TRTPN*MITTFL			N	6	3	
AVISITN*TRTPN*MITTFL			Y	6	3	
AVISITN*TRTPN*MITTFL			N	6	900	
AVISITN*TRTPN*MITTFL			Y	6	900	
AVISITN*TRTPN*MITTFL			N	10	1	
AVISITN*TRTPN*MITTFL			Y	10	1	
AVISITN*TRTPN*MITTFL			N	10	2	1
AVISITN*TRTPN*MITTFL			Y	10	2	-1
AVISITN*TRTPN*MITTFL			N	10	3	
AVISITN*TRTPN*MITTFL			Y	10	3	
AVISITN*TRTPN*MITTFL			N	10	900	-1
AVISITN*TRTPN*MITTFL			Y	10	900	1
AVISITN*TRTPN*MITTFL			N	12	1	

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STAT-3.4.3
 MMRM Output for Test on Treatment by 30 Percent Improvement Subgroup Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY MITTFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*MITTFL			Y	12	1	
AVISITN*TRTPN*MITTFL			N	12	2	
AVISITN*TRTPN*MITTFL			Y	12	2	
AVISITN*TRTPN*MITTFL			N	12	3	
AVISITN*TRTPN*MITTFL			Y	12	3	
AVISITN*TRTPN*MITTFL			N	12	900	
AVISITN*TRTPN*MITTFL			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.4.3
MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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MMRM Output for Test on Treatment by [REDACTED] STAT-3.4.3
 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
MITTFL			N			
MITTFL			Y			
AVISITN*MITTFL			N	3		
AVISITN*MITTFL			Y	3		
AVISITN*MITTFL			N	6		
AVISITN*MITTFL			Y	6		
AVISITN*MITTFL			N	10		
AVISITN*MITTFL			Y	10		
AVISITN*MITTFL			N	12		
AVISITN*MITTFL			Y	12		
TRTPN*MITTFL			N		1	
TRTPN*MITTFL			Y		1	
TRTPN*MITTFL			N		2	
TRTPN*MITTFL			Y		2	
TRTPN*MITTFL			N		3	1
TRTPN*MITTFL			Y		3	-1
TRTPN*MITTFL			N		900	-1

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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*MITTFL			Y		900	1
AVISITN*TRTPN*MITTFL			N	3	1	
AVISITN*TRTPN*MITTFL			Y	3	1	
AVISITN*TRTPN*MITTFL			N	3	2	
AVISITN*TRTPN*MITTFL			Y	3	2	
AVISITN*TRTPN*MITTFL			N	3	3	
AVISITN*TRTPN*MITTFL			Y	3	3	
AVISITN*TRTPN*MITTFL			N	3	900	
AVISITN*TRTPN*MITTFL			Y	3	900	
AVISITN*TRTPN*MITTFL			N	6	1	
AVISITN*TRTPN*MITTFL			Y	6	1	
AVISITN*TRTPN*MITTFL			N	6	2	
AVISITN*TRTPN*MITTFL			Y	6	2	
AVISITN*TRTPN*MITTFL			N	6	3	
AVISITN*TRTPN*MITTFL			Y	6	3	
AVISITN*TRTPN*MITTFL			N	6	900	
AVISITN*TRTPN*MITTFL			Y	6	900	
AVISITN*TRTPN*MITTFL			N	10	1	

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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*MITTFL			Y	10	1	
AVISITN*TRTPN*MITTFL			N	10	2	
AVISITN*TRTPN*MITTFL			Y	10	2	
AVISITN*TRTPN*MITTFL			N	10	3	1
AVISITN*TRTPN*MITTFL			Y	10	3	-1
AVISITN*TRTPN*MITTFL			N	10	900	-1
AVISITN*TRTPN*MITTFL			Y	10	900	1
AVISITN*TRTPN*MITTFL			N	12	1	
AVISITN*TRTPN*MITTFL			Y	12	1	
AVISITN*TRTPN*MITTFL			N	12	2	
AVISITN*TRTPN*MITTFL			Y	12	2	
AVISITN*TRTPN*MITTFL			N	12	3	
AVISITN*TRTPN*MITTFL			Y	12	3	
AVISITN*TRTPN*MITTFL			N	12	900	
AVISITN*TRTPN*MITTFL			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.4.3
 MMRM Output for Test on Treatment by [REDACTED] 30 Percent Improvement Subgroup Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY MITTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy W vs. Dummy Z BY MITTFL AT Phase B [REDACTED]	-4.8996	4.5311	243	-1.08	0.2806
Dummy W vs. Dummy Y BY MITTFL AT Phase B [REDACTED]	6.9278	4.8487	243	1.43	0.1543
Dummy W vs. Dummy X BY MITTFL AT Phase B [REDACTED]	-2.5576	4.6911	251	-0.55	0.5861
Dummy X vs. Dummy Z BY MITTFL AT Phase B [REDACTED]	-2.3421	4.6018	246	-0.51	0.6112
Dummy Y vs. Dummy Z BY MITTFL AT Phase B [REDACTED]	-11.8274	4.7736	241	-2.48	0.0139

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STAT-3.4.3
 MMRM Output for Test on Treatment by 30 Percent Improvement Subgroup Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN*MITTFL	N	3	1	-6.3081	2.3377	281	-2.70	0.0074	0.05	-10.9098	-1.7063
AVISITN*TRTPN*MITTFL	Y	3	1	-6.4610	1.2810	283	-5.04	<.0001	0.05	-8.9824	-3.9395
AVISITN*TRTPN*MITTFL	N	3	2	-4.6231	2.3455	277	-1.97	0.0497	0.05	-9.2405	-0.00574
AVISITN*TRTPN*MITTFL	Y	3	2	-4.5219	1.4479	286	-3.12	0.0020	0.05	-7.3718	-1.6720
AVISITN*TRTPN*MITTFL	N	3	3	-10.4830	2.4267	274	-4.32	<.0001	0.05	-15.2604	-5.7056
AVISITN*TRTPN*MITTFL	Y	3	3	-4.9620	1.2964	282	-3.83	0.0002	0.05	-7.5137	-2.4102
AVISITN*TRTPN*MITTFL	N	3	900	-4.5495	2.3128	275	-1.97	0.0502	0.05	-9.1026	0.003519
AVISITN*TRTPN*MITTFL	Y	3	900	-6.7297	1.2793	283	-5.26	<.0001	0.05	-9.2479	-4.2115
AVISITN*TRTPN*MITTFL	N	6	1	-12.9429	2.9131	266	-4.44	<.0001	0.05	-18.6785	-7.2073
AVISITN*TRTPN*MITTFL	Y	6	1	-12.5088	1.5915	272	-7.86	<.0001	0.05	-15.6421	-9.3755
AVISITN*TRTPN*MITTFL	N	6	2	-5.4177	3.0993	287	-1.75	0.0815	0.05	-11.5180	0.6826
AVISITN*TRTPN*MITTFL	Y	6	2	-8.8230	1.7357	278	-5.08	<.0001	0.05	-12.2398	-5.4062
AVISITN*TRTPN*MITTFL	N	6	3	-14.1987	3.2353	270	-4.39	<.0001	0.05	-20.5682	-7.8291
AVISITN*TRTPN*MITTFL	Y	6	3	-8.5272	1.5912	281	-5.36	<.0001	0.05	-11.6595	-5.3950
AVISITN*TRTPN*MITTFL	N	6	900	-6.7102	2.8408	253	-2.36	0.0189	0.05	-12.3048	-1.1156
AVISITN*TRTPN*MITTFL	Y	6	900	-9.5101	1.5471	272	-6.15	<.0001	0.05	-12.5559	-6.4643
AVISITN*TRTPN*MITTFL	N	10	1	-16.6564	3.2365	255	-5.15	<.0001	0.05	-23.0301	-10.2828
AVISITN*TRTPN*MITTFL	Y	10	1	-16.3297	1.6978	242	-9.62	<.0001	0.05	-19.6740	-12.9854

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STAT-3.4.3
 MMRM Output for Test on Treatment by 30 Percent Improvement Subgroup Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	Modified ITT Population Flag	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN*MITTFL	N	10	2	-10.5106	3.3829	262	-3.11	0.0021	0.05	-17.1718	-3.8494
AVISITN*TRTPN*MITTFL	Y	10	2	-12.7414	1.9093	271	-6.67	<.0001	0.05	-16.5004	-8.9825
AVISITN*TRTPN*MITTFL	N	10	3	-17.1670	3.5139	239	-4.89	<.0001	0.05	-24.0891	-10.2448
AVISITN*TRTPN*MITTFL	Y	10	3	-9.9125	1.6933	253	-5.85	<.0001	0.05	-13.2473	-6.5776
AVISITN*TRTPN*MITTFL	N	10	900	-6.9406	3.1049	240	-2.24	0.0263	0.05	-13.0569	-0.8243
AVISITN*TRTPN*MITTFL	Y	10	900	-11.5135	1.6552	252	-6.96	<.0001	0.05	-14.7732	-8.2538
AVISITN*TRTPN*MITTFL	N	12	1	-17.3439	3.5556	257	-4.88	<.0001	0.05	-24.3457	-10.3420
AVISITN*TRTPN*MITTFL	Y	12	1	-17.2586	1.8696	249	-9.23	<.0001	0.05	-20.9409	-13.5763
AVISITN*TRTPN*MITTFL	N	12	2	-8.7967	3.7268	263	-2.36	0.0190	0.05	-16.1349	-1.4585
AVISITN*TRTPN*MITTFL	Y	12	2	-13.3994	2.0839	270	-6.43	<.0001	0.05	-17.5022	-9.2967
AVISITN*TRTPN*MITTFL	N	12	3	-18.9200	3.8443	242	-4.92	<.0001	0.05	-26.4925	-11.3474
AVISITN*TRTPN*MITTFL	Y	12	3	-13.9110	1.8371	253	-7.57	<.0001	0.05	-17.5290	-10.2931
AVISITN*TRTPN*MITTFL	N	12	900	-8.3293	3.4638	252	-2.40	0.0169	0.05	-15.1509	-1.5077
AVISITN*TRTPN*MITTFL	Y	12	900	-12.6593	1.8062	253	-7.01	<.0001	0.05	-16.2163	-9.1022

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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
AVISITN	4	3 6 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	[REDACTED]
COMBFL	2	N Y

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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	299	

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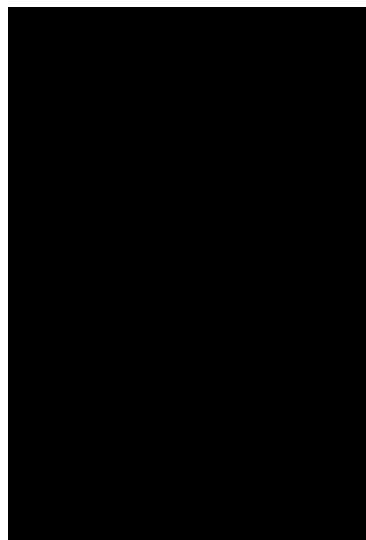
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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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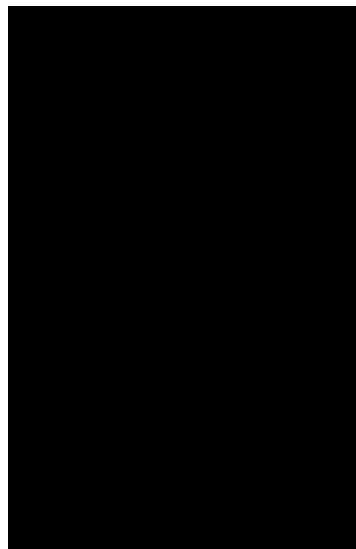
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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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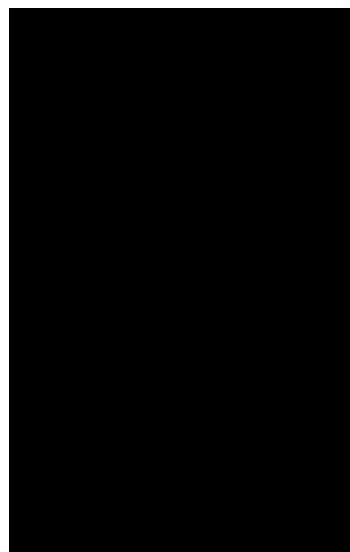
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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

COMBFL 2 N Y

Dimensions

Covariance Parameters	10
Columns in X	89
Columns in Z	0
Subjects	299
Max Obs per Subject	4

Number of Observations

Number of Observations Read	996
Number of Observations Used	996
Number of Observations Not Used	0

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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	7329.71676721	
1	2	6852.58631754	0.00163324
2	1	6847.71408270	0.00016830
3	1	6847.25354259	0.00000244
4	1	6847.24725471	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	78.2606
UN(2,1)	SUBJID	52.8071
UN(2,2)	SUBJID	113.16
UN(3,1)	SUBJID	43.3385
UN(3,2)	SUBJID	90.7080
UN(3,3)	SUBJID	121.79
UN(4,1)	SUBJID	47.2805

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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,2)	SUBJID	89.4682
UN(4,3)	SUBJID	103.52
UN(4,4)	SUBJID	145.27

Fit Statistics

-2 Res Log Likelihood	6847.2
AIC (Smaller is Better)	6867.2
AICC (Smaller is Better)	6867.5
BIC (Smaller is Better)	6904.3

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
9	482.47	<.0001

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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
POOLCNTR	9	278	1.71	0.0866
COMBFL	1	283	1.93	0.1661
AVISITN	3	230	0.94	0.4225
TRTPN	3	276	2.45	0.0636
AVISITN*TRTPN	9	367	1.84	0.0596
AVISITN*COMBFL	3	243	2.95	0.0336
TRTPN*COMBFL	3	277	1.00	0.3943
AVISITN*TRTPN*COMBFL	9	367	1.97	0.0421
BASE*AVISITN	4	240	15.22	<.0001

Coefficients for Dummy W vs. Dummy Z BY COMBFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept					
POOLCNTR					

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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY COMBFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
COMBFL		N			
COMBFL		Y			
AVISITN			3		
AVISITN			6		
AVISITN			10		
AVISITN			12		
TRTPN				1	
TRTPN				2	
TRTPN				3	

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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY COMBFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN				900	
AVISITN*TRTPN			3	1	
AVISITN*TRTPN			3	2	
AVISITN*TRTPN			3	3	
AVISITN*TRTPN			3	900	
AVISITN*TRTPN			6	1	
AVISITN*TRTPN			6	2	
AVISITN*TRTPN			6	3	
AVISITN*TRTPN			6	900	
AVISITN*TRTPN			10	1	
AVISITN*TRTPN			10	2	
AVISITN*TRTPN			10	3	
AVISITN*TRTPN			10	900	
AVISITN*TRTPN			12	1	
AVISITN*TRTPN			12	2	
AVISITN*TRTPN			12	3	
AVISITN*TRTPN			12	900	
AVISITN*COMBFL		N	3		

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY COMBFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*COMBFL		Y	3		
AVISITN*COMBFL		N	6		
AVISITN*COMBFL		Y	6		
AVISITN*COMBFL		N	10		
AVISITN*COMBFL		Y	10		
AVISITN*COMBFL		N	12		
AVISITN*COMBFL		Y	12		
TRTPN*COMBFL		N		1	1
TRTPN*COMBFL		Y		1	-1
TRTPN*COMBFL		N		2	
TRTPN*COMBFL		Y		2	
TRTPN*COMBFL		N		3	
TRTPN*COMBFL		Y		3	
TRTPN*COMBFL		N		900	-1
TRTPN*COMBFL		Y		900	1
AVISITN*TRTPN*COMBFL		N	3	1	
AVISITN*TRTPN*COMBFL		Y	3	1	
AVISITN*TRTPN*COMBFL		N	3	2	

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY COMBFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*COMBFL		Y	3	2	
AVISITN*TRTPN*COMBFL		N	3	3	
AVISITN*TRTPN*COMBFL		Y	3	3	
AVISITN*TRTPN*COMBFL		N	3	900	
AVISITN*TRTPN*COMBFL		Y	3	900	
AVISITN*TRTPN*COMBFL		N	6	1	
AVISITN*TRTPN*COMBFL		Y	6	1	
AVISITN*TRTPN*COMBFL		N	6	2	
AVISITN*TRTPN*COMBFL		Y	6	2	
AVISITN*TRTPN*COMBFL		N	6	3	
AVISITN*TRTPN*COMBFL		Y	6	3	
AVISITN*TRTPN*COMBFL		N	6	900	
AVISITN*TRTPN*COMBFL		Y	6	900	
AVISITN*TRTPN*COMBFL		N	10	1	1
AVISITN*TRTPN*COMBFL		Y	10	1	-1
AVISITN*TRTPN*COMBFL		N	10	2	
AVISITN*TRTPN*COMBFL		Y	10	2	
AVISITN*TRTPN*COMBFL		N	10	3	

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 MMRM Output for Test on Treatment by Type of Trauma Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY COMBFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*COMBFL		Y	10	3	
AVISITN*TRTPN*COMBFL		N	10	900	-1
AVISITN*TRTPN*COMBFL		Y	10	900	1
AVISITN*TRTPN*COMBFL		N	12	1	
AVISITN*TRTPN*COMBFL		Y	12	1	
AVISITN*TRTPN*COMBFL		N	12	2	
AVISITN*TRTPN*COMBFL		Y	12	2	
AVISITN*TRTPN*COMBFL		N	12	3	
AVISITN*TRTPN*COMBFL		Y	12	3	
AVISITN*TRTPN*COMBFL		N	12	900	
AVISITN*TRTPN*COMBFL		Y	12	900	
BASE*AVISITN			3		
BASE*AVISITN			6		
BASE*AVISITN			10		
BASE*AVISITN			12		

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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY COMBFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
COMBFL		N			
COMBFL		Y			
AVISITN			3		
AVISITN			6		
AVISITN			10		
AVISITN			12		
TRTPN				1	

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY COMBFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN				2	
TRTPN				3	
TRTPN				900	
AVISITN*TRTPN			3	1	
AVISITN*TRTPN			3	2	
AVISITN*TRTPN			3	3	
AVISITN*TRTPN			3	900	
AVISITN*TRTPN			6	1	
AVISITN*TRTPN			6	2	
AVISITN*TRTPN			6	3	
AVISITN*TRTPN			6	900	
AVISITN*TRTPN			10	1	
AVISITN*TRTPN			10	2	
AVISITN*TRTPN			10	3	
AVISITN*TRTPN			10	900	
AVISITN*TRTPN			12	1	
AVISITN*TRTPN			12	2	
AVISITN*TRTPN			12	3	

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY COMBFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN			12	900	
AVISITN*COMBFL		N	3		
AVISITN*COMBFL		Y	3		
AVISITN*COMBFL		N	6		
AVISITN*COMBFL		Y	6		
AVISITN*COMBFL		N	10		
AVISITN*COMBFL		Y	10		
AVISITN*COMBFL		N	12		
AVISITN*COMBFL		Y	12		
TRTPN*COMBFL		N		1	1
TRTPN*COMBFL		Y		1	-1
TRTPN*COMBFL		N		2	
TRTPN*COMBFL		Y		2	
TRTPN*COMBFL		N		3	-1
TRTPN*COMBFL		Y		3	1
TRTPN*COMBFL		N		900	
TRTPN*COMBFL		Y		900	
AVISITN*TRTPN*COMBFL		N	3	1	

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 (Intent to Treat Sample)

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The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY COMBFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*COMBFL		Y	3	1	
AVISITN*TRTPN*COMBFL		N	3	2	
AVISITN*TRTPN*COMBFL		Y	3	2	
AVISITN*TRTPN*COMBFL		N	3	3	
AVISITN*TRTPN*COMBFL		Y	3	3	
AVISITN*TRTPN*COMBFL		N	3	900	
AVISITN*TRTPN*COMBFL		Y	3	900	
AVISITN*TRTPN*COMBFL		N	6	1	
AVISITN*TRTPN*COMBFL		Y	6	1	
AVISITN*TRTPN*COMBFL		N	6	2	
AVISITN*TRTPN*COMBFL		Y	6	2	
AVISITN*TRTPN*COMBFL		N	6	3	
AVISITN*TRTPN*COMBFL		Y	6	3	
AVISITN*TRTPN*COMBFL		N	6	900	
AVISITN*TRTPN*COMBFL		Y	6	900	
AVISITN*TRTPN*COMBFL		N	10	1	1
AVISITN*TRTPN*COMBFL		Y	10	1	-1
AVISITN*TRTPN*COMBFL		N	10	2	

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MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY COMBFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*COMBFL		Y	10	2	
AVISITN*TRTPN*COMBFL		N	10	3	-1
AVISITN*TRTPN*COMBFL		Y	10	3	1
AVISITN*TRTPN*COMBFL		N	10	900	
AVISITN*TRTPN*COMBFL		Y	10	900	
AVISITN*TRTPN*COMBFL		N	12	1	
AVISITN*TRTPN*COMBFL		Y	12	1	
AVISITN*TRTPN*COMBFL		N	12	2	
AVISITN*TRTPN*COMBFL		Y	12	2	
AVISITN*TRTPN*COMBFL		N	12	3	
AVISITN*TRTPN*COMBFL		Y	12	3	
AVISITN*TRTPN*COMBFL		N	12	900	
AVISITN*TRTPN*COMBFL		Y	12	900	
BASE*AVISITN			3		
BASE*AVISITN			6		
BASE*AVISITN			10		
BASE*AVISITN			12		

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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY COMBFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
COMBFL		N			
COMBFL		Y			
AVISITN			3		
AVISITN			6		
AVISITN			10		
AVISITN			12		
TRTPN				1	

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY COMBFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN				2	
TRTPN				3	
TRTPN				900	
AVISITN*TRTPN			3	1	
AVISITN*TRTPN			3	2	
AVISITN*TRTPN			3	3	
AVISITN*TRTPN			3	900	
AVISITN*TRTPN			6	1	
AVISITN*TRTPN			6	2	
AVISITN*TRTPN			6	3	
AVISITN*TRTPN			6	900	
AVISITN*TRTPN			10	1	
AVISITN*TRTPN			10	2	
AVISITN*TRTPN			10	3	
AVISITN*TRTPN			10	900	
AVISITN*TRTPN			12	1	
AVISITN*TRTPN			12	2	
AVISITN*TRTPN			12	3	

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY COMBFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN			12	900	
AVISITN*COMBFL		N	3		
AVISITN*COMBFL		Y	3		
AVISITN*COMBFL		N	6		
AVISITN*COMBFL		Y	6		
AVISITN*COMBFL		N	10		
AVISITN*COMBFL		Y	10		
AVISITN*COMBFL		N	12		
AVISITN*COMBFL		Y	12		
TRTPN*COMBFL		N		1	1
TRTPN*COMBFL		Y		1	-1
TRTPN*COMBFL		N		2	-1
TRTPN*COMBFL		Y		2	1
TRTPN*COMBFL		N		3	
TRTPN*COMBFL		Y		3	
TRTPN*COMBFL		N		900	
TRTPN*COMBFL		Y		900	
AVISITN*TRTPN*COMBFL		N	3	1	

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY COMBFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*COMBFL		Y	3	1	
AVISITN*TRTPN*COMBFL		N	3	2	
AVISITN*TRTPN*COMBFL		Y	3	2	
AVISITN*TRTPN*COMBFL		N	3	3	
AVISITN*TRTPN*COMBFL		Y	3	3	
AVISITN*TRTPN*COMBFL		N	3	900	
AVISITN*TRTPN*COMBFL		Y	3	900	
AVISITN*TRTPN*COMBFL		N	6	1	
AVISITN*TRTPN*COMBFL		Y	6	1	
AVISITN*TRTPN*COMBFL		N	6	2	
AVISITN*TRTPN*COMBFL		Y	6	2	
AVISITN*TRTPN*COMBFL		N	6	3	
AVISITN*TRTPN*COMBFL		Y	6	3	
AVISITN*TRTPN*COMBFL		N	6	900	
AVISITN*TRTPN*COMBFL		Y	6	900	
AVISITN*TRTPN*COMBFL		N	10	1	1
AVISITN*TRTPN*COMBFL		Y	10	1	-1
AVISITN*TRTPN*COMBFL		N	10	2	-1

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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY COMBFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*COMBFL		Y	10	2	1
AVISITN*TRTPN*COMBFL		N	10	3	
AVISITN*TRTPN*COMBFL		Y	10	3	
AVISITN*TRTPN*COMBFL		N	10	900	
AVISITN*TRTPN*COMBFL		Y	10	900	
AVISITN*TRTPN*COMBFL		N	12	1	
AVISITN*TRTPN*COMBFL		Y	12	1	
AVISITN*TRTPN*COMBFL		N	12	2	
AVISITN*TRTPN*COMBFL		Y	12	2	
AVISITN*TRTPN*COMBFL		N	12	3	
AVISITN*TRTPN*COMBFL		Y	12	3	
AVISITN*TRTPN*COMBFL		N	12	900	
AVISITN*TRTPN*COMBFL		Y	12	900	
BASE*AVISITN			3		
BASE*AVISITN			6		
BASE*AVISITN			10		
BASE*AVISITN			12		

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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY COMBFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]				
POOLCNTR					
POOLCNTR					
POOLCNTR					
POOLCNTR					
POOLCNTR					
POOLCNTR					
POOLCNTR					
POOLCNTR					
POOLCNTR					
POOLCNTR					
POOLCNTR					
COMBFL		N			
COMBFL		Y			
AVISITN			3		
AVISITN			6		
AVISITN			10		
AVISITN			12		
TRTPN				1	

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY COMBFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN				2	
TRTPN				3	
TRTPN				900	
AVISITN*TRTPN			3	1	
AVISITN*TRTPN			3	2	
AVISITN*TRTPN			3	3	
AVISITN*TRTPN			3	900	
AVISITN*TRTPN			6	1	
AVISITN*TRTPN			6	2	
AVISITN*TRTPN			6	3	
AVISITN*TRTPN			6	900	
AVISITN*TRTPN			10	1	
AVISITN*TRTPN			10	2	
AVISITN*TRTPN			10	3	
AVISITN*TRTPN			10	900	
AVISITN*TRTPN			12	1	
AVISITN*TRTPN			12	2	
AVISITN*TRTPN			12	3	

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY COMBFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN			12	900	
AVISITN*COMBFL		N	3		
AVISITN*COMBFL		Y	3		
AVISITN*COMBFL		N	6		
AVISITN*COMBFL		Y	6		
AVISITN*COMBFL		N	10		
AVISITN*COMBFL		Y	10		
AVISITN*COMBFL		N	12		
AVISITN*COMBFL		Y	12		
TRTPN*COMBFL		N		1	
TRTPN*COMBFL		Y		1	
TRTPN*COMBFL		N		2	1
TRTPN*COMBFL		Y		2	-1
TRTPN*COMBFL		N		3	
TRTPN*COMBFL		Y		3	
TRTPN*COMBFL		N		900	-1
TRTPN*COMBFL		Y		900	1
AVISITN*TRTPN*COMBFL		N	3	1	

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY COMBFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*COMBFL		Y	3	1	
AVISITN*TRTPN*COMBFL		N	3	2	
AVISITN*TRTPN*COMBFL		Y	3	2	
AVISITN*TRTPN*COMBFL		N	3	3	
AVISITN*TRTPN*COMBFL		Y	3	3	
AVISITN*TRTPN*COMBFL		N	3	900	
AVISITN*TRTPN*COMBFL		Y	3	900	
AVISITN*TRTPN*COMBFL		N	6	1	
AVISITN*TRTPN*COMBFL		Y	6	1	
AVISITN*TRTPN*COMBFL		N	6	2	
AVISITN*TRTPN*COMBFL		Y	6	2	
AVISITN*TRTPN*COMBFL		N	6	3	
AVISITN*TRTPN*COMBFL		Y	6	3	
AVISITN*TRTPN*COMBFL		N	6	900	
AVISITN*TRTPN*COMBFL		Y	6	900	
AVISITN*TRTPN*COMBFL		N	10	1	
AVISITN*TRTPN*COMBFL		Y	10	1	
AVISITN*TRTPN*COMBFL		N	10	2	1

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY COMBFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*COMBFL		Y	10	2	-1
AVISITN*TRTPN*COMBFL		N	10	3	
AVISITN*TRTPN*COMBFL		Y	10	3	
AVISITN*TRTPN*COMBFL		N	10	900	-1
AVISITN*TRTPN*COMBFL		Y	10	900	1
AVISITN*TRTPN*COMBFL		N	12	1	
AVISITN*TRTPN*COMBFL		Y	12	1	
AVISITN*TRTPN*COMBFL		N	12	2	
AVISITN*TRTPN*COMBFL		Y	12	2	
AVISITN*TRTPN*COMBFL		N	12	3	
AVISITN*TRTPN*COMBFL		Y	12	3	
AVISITN*TRTPN*COMBFL		N	12	900	
AVISITN*TRTPN*COMBFL		Y	12	900	
BASE*AVISITN			3		
BASE*AVISITN			6		
BASE*AVISITN			10		
BASE*AVISITN			12		

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BREXPIRAZOLE
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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY COMBFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
POOLCNTR	[REDACTED]				
COMBFL		N			
COMBFL		Y			
AVISITN			3		
AVISITN			6		
AVISITN			10		
AVISITN			12		
TRTPN				1	

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY COMBFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN				2	
TRTPN				3	
TRTPN				900	
AVISITN*TRTPN			3	1	
AVISITN*TRTPN			3	2	
AVISITN*TRTPN			3	3	
AVISITN*TRTPN			3	900	
AVISITN*TRTPN			6	1	
AVISITN*TRTPN			6	2	
AVISITN*TRTPN			6	3	
AVISITN*TRTPN			6	900	
AVISITN*TRTPN			10	1	
AVISITN*TRTPN			10	2	
AVISITN*TRTPN			10	3	
AVISITN*TRTPN			10	900	
AVISITN*TRTPN			12	1	
AVISITN*TRTPN			12	2	
AVISITN*TRTPN			12	3	

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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY COMBFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN			12	900	
AVISITN*COMBFL		N	3		
AVISITN*COMBFL		Y	3		
AVISITN*COMBFL		N	6		
AVISITN*COMBFL		Y	6		
AVISITN*COMBFL		N	10		
AVISITN*COMBFL		Y	10		
AVISITN*COMBFL		N	12		
AVISITN*COMBFL		Y	12		
TRTPN*COMBFL		N		1	
TRTPN*COMBFL		Y		1	
TRTPN*COMBFL		N		2	
TRTPN*COMBFL		Y		2	
TRTPN*COMBFL		N		3	1
TRTPN*COMBFL		Y		3	-1
TRTPN*COMBFL		N		900	-1
TRTPN*COMBFL		Y		900	1
AVISITN*TRTPN*COMBFL		N	3	1	

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY COMBFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*COMBFL		Y	3	1	
AVISITN*TRTPN*COMBFL		N	3	2	
AVISITN*TRTPN*COMBFL		Y	3	2	
AVISITN*TRTPN*COMBFL		N	3	3	
AVISITN*TRTPN*COMBFL		Y	3	3	
AVISITN*TRTPN*COMBFL		N	3	900	
AVISITN*TRTPN*COMBFL		Y	3	900	
AVISITN*TRTPN*COMBFL		N	6	1	
AVISITN*TRTPN*COMBFL		Y	6	1	
AVISITN*TRTPN*COMBFL		N	6	2	
AVISITN*TRTPN*COMBFL		Y	6	2	
AVISITN*TRTPN*COMBFL		N	6	3	
AVISITN*TRTPN*COMBFL		Y	6	3	
AVISITN*TRTPN*COMBFL		N	6	900	
AVISITN*TRTPN*COMBFL		Y	6	900	
AVISITN*TRTPN*COMBFL		N	10	1	
AVISITN*TRTPN*COMBFL		Y	10	1	
AVISITN*TRTPN*COMBFL		N	10	2	

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STAT-3.5
MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY COMBFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*COMBFL		Y	10	2	
AVISITN*TRTPN*COMBFL		N	10	3	1
AVISITN*TRTPN*COMBFL		Y	10	3	-1
AVISITN*TRTPN*COMBFL		N	10	900	-1
AVISITN*TRTPN*COMBFL		Y	10	900	1
AVISITN*TRTPN*COMBFL		N	12	1	
AVISITN*TRTPN*COMBFL		Y	12	1	
AVISITN*TRTPN*COMBFL		N	12	2	
AVISITN*TRTPN*COMBFL		Y	12	2	
AVISITN*TRTPN*COMBFL		N	12	3	
AVISITN*TRTPN*COMBFL		Y	12	3	
AVISITN*TRTPN*COMBFL		N	12	900	
AVISITN*TRTPN*COMBFL		Y	12	900	
BASE*AVISITN			3		
BASE*AVISITN			6		
BASE*AVISITN			10		
BASE*AVISITN			12		

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy W vs. Dummy Z BY COMBFL AT Phase B [REDACTED]	-1.2786	4.4667	234	-0.29	0.7749
Dummy W vs. Dummy Y BY COMBFL AT Phase B [REDACTED]	-9.1358	4.7247	239	-1.93	0.0543
Dummy W vs. Dummy X BY COMBFL AT Phase B [REDACTED]	-4.6175	5.7957	277	-0.80	0.4263
Dummy X vs. Dummy Z BY COMBFL AT Phase B [REDACTED]	3.3389	5.7779	276	0.58	0.5638
Dummy Y vs. Dummy Z BY COMBFL AT Phase B [REDACTED]	7.8572	4.6952	237	1.67	0.0956

Least Squares Means

Effect	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN*COMBFL	N	3	1	-5.4540	1.1912	281	-4.58	<.0001	0.05	-7.7987	-3.1092
AVISITN*TRTPN*COMBFL	Y	3	1	-6.8538	2.1684	285	-3.16	0.0017	0.05	-11.1219	-2.5856
AVISITN*TRTPN*COMBFL	N	3	2	-2.9761	1.2129	282	-2.45	0.0147	0.05	-5.3635	-0.5886
AVISITN*TRTPN*COMBFL	Y	3	2	-7.6297	2.6776	274	-2.85	0.0047	0.05	-12.9010	-2.3585
AVISITN*TRTPN*COMBFL	N	3	3	-4.2773	1.1856	280	-3.61	0.0004	0.05	-6.6112	-1.9434
AVISITN*TRTPN*COMBFL	Y	3	3	-10.1529	2.2995	275	-4.42	<.0001	0.05	-14.6799	-5.6260

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN*COMBFL	N	3	900	-5.1726	1.1632	278	-4.45	<.0001	0.05	-7.4624	-2.8828
AVISITN*TRTPN*COMBFL	Y	3	900	-6.7476	2.1589	275	-3.13	0.0020	0.05	-10.9976	-2.4975
AVISITN*TRTPN*COMBFL	N	6	1	-10.4557	1.4952	269	-6.99	<.0001	0.05	-13.3995	-7.5119
AVISITN*TRTPN*COMBFL	Y	6	1	-16.6958	2.6125	258	-6.39	<.0001	0.05	-21.8402	-11.5513
AVISITN*TRTPN*COMBFL	N	6	2	-6.5897	1.4640	261	-4.50	<.0001	0.05	-9.4724	-3.7071
AVISITN*TRTPN*COMBFL	Y	6	2	-9.8529	3.9562	295	-2.49	0.0133	0.05	-17.6388	-2.0669
AVISITN*TRTPN*COMBFL	N	6	3	-8.2770	1.4793	269	-5.60	<.0001	0.05	-11.1895	-5.3645
AVISITN*TRTPN*COMBFL	Y	6	3	-11.3745	2.9953	277	-3.80	0.0002	0.05	-17.2709	-5.4781
AVISITN*TRTPN*COMBFL	N	6	900	-8.3156	1.4333	260	-5.80	<.0001	0.05	-11.1380	-5.4932
AVISITN*TRTPN*COMBFL	Y	6	900	-7.8831	2.6189	250	-3.01	0.0029	0.05	-13.0410	-2.7251
AVISITN*TRTPN*COMBFL	N	10	1	-16.9149	1.5914	246	-10.63	<.0001	0.05	-20.0495	-13.7803
AVISITN*TRTPN*COMBFL	Y	10	1	-12.5091	2.7575	234	-4.54	<.0001	0.05	-17.9419	-7.0763
AVISITN*TRTPN*COMBFL	N	10	2	-11.0599	1.5761	250	-7.02	<.0001	0.05	-14.1640	-7.9559
AVISITN*TRTPN*COMBFL	Y	10	2	-11.2716	4.5968	298	-2.45	0.0148	0.05	-20.3178	-2.2254
AVISITN*TRTPN*COMBFL	N	10	3	-9.6659	1.5697	245	-6.16	<.0001	0.05	-12.7578	-6.5740
AVISITN*TRTPN*COMBFL	Y	10	3	-14.3958	3.1301	242	-4.60	<.0001	0.05	-20.5615	-8.2301
AVISITN*TRTPN*COMBFL	N	10	900	-10.5054	1.5308	244	-6.86	<.0001	0.05	-13.5206	-7.4902
AVISITN*TRTPN*COMBFL	Y	10	900	-7.3782	2.7598	230	-2.67	0.0080	0.05	-12.8159	-1.9405

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STAT-3.5
 MMRM Output for Test on Treatment by Type of Trauma Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN*COMBFL	N	12	1	-16.3362	1.7475	243	-9.35	<.0001	0.05	-19.7785	-12.8939
AVISITN*TRTPN*COMBFL	Y	12	1	-17.6543	3.1212	245	-5.66	<.0001	0.05	-23.8021	-11.5066
AVISITN*TRTPN*COMBFL	N	12	2	-11.0683	1.7448	249	-6.34	<.0001	0.05	-14.5047	-7.6319
AVISITN*TRTPN*COMBFL	Y	12	2	-11.9169	4.8874	264	-2.44	0.0154	0.05	-21.5400	-2.2938
AVISITN*TRTPN*COMBFL	N	12	3	-12.5249	1.7188	242	-7.29	<.0001	0.05	-15.9106	-9.1392
AVISITN*TRTPN*COMBFL	Y	12	3	-20.8155	3.4460	240	-6.04	<.0001	0.05	-27.6037	-14.0273
AVISITN*TRTPN*COMBFL	N	12	900	-11.3141	1.6739	239	-6.76	<.0001	0.05	-14.6115	-8.0167
AVISITN*TRTPN*COMBFL	Y	12	900	-9.7796	3.1245	243	-3.13	0.0020	0.05	-15.9342	-3.6250

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STAT-3.6
MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
AVISITN	4	3 6 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	[REDACTED]
COMBFL	2	N Y

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STAT-3.6
MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	299	

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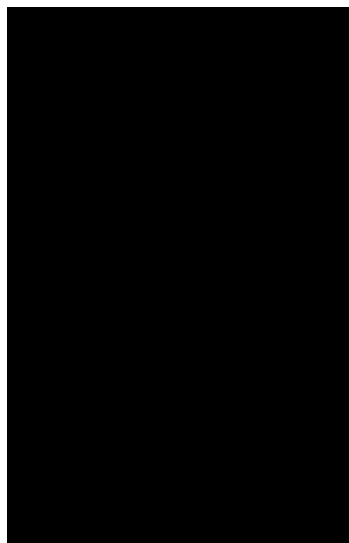
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STAT-3.6
MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction [REDACTED]
(Intent to Treat Sample)

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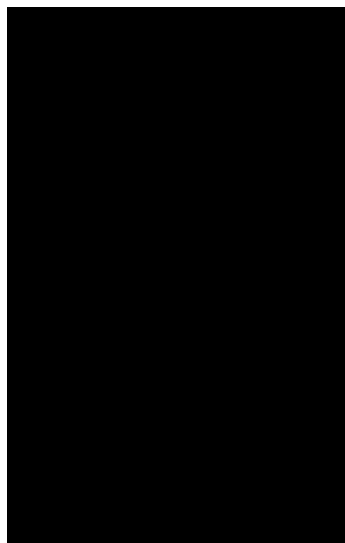
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STAT-3.6
MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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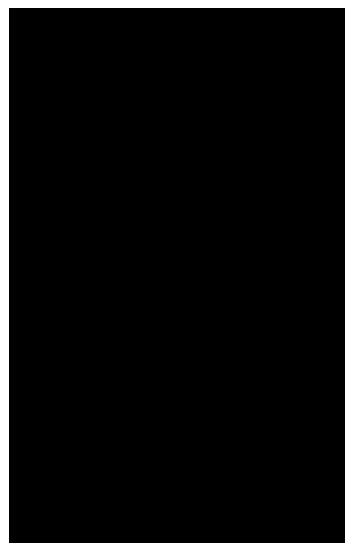
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STAT-3.6
MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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STAT-3.6
MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

PSYCHFL 2 N Y

Dimensions

Covariance Parameters	10
Columns in X	91
Columns in Z	0
Subjects	299
Max Obs per Subject	4

Number of Observations

Number of Observations Read	996
Number of Observations Used	996
Number of Observations Not Used	0

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STAT-3.6
MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	7347.29266401	
1	2	6871.95746428	0.00046015
2	1	6870.65074164	0.00001625
3	1	6870.60806155	0.00000002
4	1	6870.60799804	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	78.0946
UN(2,1)	SUBJID	51.6582
UN(2,2)	SUBJID	112.64
UN(3,1)	SUBJID	43.7333
UN(3,2)	SUBJID	89.6240
UN(3,3)	SUBJID	125.14
UN(4,1)	SUBJID	48.6156

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STAT-3.6
MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,2)	SUBJID	90.8869
UN(4,3)	SUBJID	107.04
UN(4,4)	SUBJID	149.19

Fit Statistics

-2 Res Log Likelihood	6870.6
AIC (Smaller is Better)	6890.6
AICC (Smaller is Better)	6890.8
BIC (Smaller is Better)	6927.6

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
9	476.68	<.0001

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STAT-3.6
MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
POOLCNTR	9	277	1.65	0.1002
COMBFL	1	278	4.02	0.0460
AVISITN	3	228	1.04	0.3774
TRTPN	3	262	3.34	0.0199
AVISITN*TRTPN	9	358	1.91	0.0491
PSYCHFL	1	280	0.62	0.4325
AVISITN*PSYCHFL	3	235	0.96	0.4119
TRTPN*PSYCHFL	3	264	0.85	0.4671
AVISIT*TRTPN*PSYCHFL	9	358	0.87	0.5500
BASE*AVISITN	4	241	15.47	<.0001

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STAT-3.6
MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY PSYCHFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
PSYCHFL			N			
PSYCHFL			Y			
AVISITN*PSYCHFL			N	3		
AVISITN*PSYCHFL			Y	3		
AVISITN*PSYCHFL			N	6		
AVISITN*PSYCHFL			Y	6		
AVISITN*PSYCHFL			N	10		
AVISITN*PSYCHFL			Y	10		
AVISITN*PSYCHFL			N	12		
AVISITN*PSYCHFL			Y	12		
TRTPN*PSYCHFL			N		1	1
TRTPN*PSYCHFL			Y		1	-1
TRTPN*PSYCHFL			N		2	
TRTPN*PSYCHFL			Y		2	
TRTPN*PSYCHFL			N		3	
TRTPN*PSYCHFL			Y		3	
TRTPN*PSYCHFL			N		900	-1

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*PSYCHFL			Y		900	1
AVISIT*TRTPN*PSYCHFL			N	3	1	
AVISIT*TRTPN*PSYCHFL			Y	3	1	
AVISIT*TRTPN*PSYCHFL			N	3	2	
AVISIT*TRTPN*PSYCHFL			Y	3	2	
AVISIT*TRTPN*PSYCHFL			N	3	3	
AVISIT*TRTPN*PSYCHFL			Y	3	3	
AVISIT*TRTPN*PSYCHFL			N	3	900	
AVISIT*TRTPN*PSYCHFL			Y	3	900	
AVISIT*TRTPN*PSYCHFL			N	6	1	
AVISIT*TRTPN*PSYCHFL			Y	6	1	
AVISIT*TRTPN*PSYCHFL			N	6	2	
AVISIT*TRTPN*PSYCHFL			Y	6	2	
AVISIT*TRTPN*PSYCHFL			N	6	3	
AVISIT*TRTPN*PSYCHFL			Y	6	3	
AVISIT*TRTPN*PSYCHFL			N	6	900	
AVISIT*TRTPN*PSYCHFL			Y	6	900	
AVISIT*TRTPN*PSYCHFL			N	10	1	1

FILE: stat2f.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*PSYCHFL			Y	10	1	-1
AVISIT*TRTPN*PSYCHFL			N	10	2	
AVISIT*TRTPN*PSYCHFL			Y	10	2	
AVISIT*TRTPN*PSYCHFL			N	10	3	
AVISIT*TRTPN*PSYCHFL			Y	10	3	
AVISIT*TRTPN*PSYCHFL			N	10	900	-1
AVISIT*TRTPN*PSYCHFL			Y	10	900	1
AVISIT*TRTPN*PSYCHFL			N	12	1	
AVISIT*TRTPN*PSYCHFL			Y	12	1	
AVISIT*TRTPN*PSYCHFL			N	12	2	
AVISIT*TRTPN*PSYCHFL			Y	12	2	
AVISIT*TRTPN*PSYCHFL			N	12	3	
AVISIT*TRTPN*PSYCHFL			Y	12	3	
AVISIT*TRTPN*PSYCHFL			N	12	900	
AVISIT*TRTPN*PSYCHFL			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.6
MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY PSYCHFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Coefficients for Dummy W vs. Dummy Y BY PSYCHFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction [REDACTED]
 (Intent to Treat Sample)

 Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY PSYCHFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	

FILE: stat2f.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
PSYCHFL			N			
PSYCHFL			Y			
AVISITN*PSYCHFL			N	3		
AVISITN*PSYCHFL			Y	3		
AVISITN*PSYCHFL			N	6		
AVISITN*PSYCHFL			Y	6		
AVISITN*PSYCHFL			N	10		

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*PSYCHFL			Y	10		
AVISITN*PSYCHFL			N	12		
AVISITN*PSYCHFL			Y	12		
TRTPN*PSYCHFL			N		1	1
TRTPN*PSYCHFL			Y		1	-1
TRTPN*PSYCHFL			N		2	
TRTPN*PSYCHFL			Y		2	
TRTPN*PSYCHFL			N		3	-1
TRTPN*PSYCHFL			Y		3	1
TRTPN*PSYCHFL			N		900	
TRTPN*PSYCHFL			Y		900	
AVISIT*TRTPN*PSYCHFL			N	3	1	
AVISIT*TRTPN*PSYCHFL			Y	3	1	
AVISIT*TRTPN*PSYCHFL			N	3	2	
AVISIT*TRTPN*PSYCHFL			Y	3	2	
AVISIT*TRTPN*PSYCHFL			N	3	3	
AVISIT*TRTPN*PSYCHFL			Y	3	3	
AVISIT*TRTPN*PSYCHFL			N	3	900	

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 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*PSYCHFL			Y	3	900	
AVISIT*TRTPN*PSYCHFL			N	6	1	
AVISIT*TRTPN*PSYCHFL			Y	6	1	
AVISIT*TRTPN*PSYCHFL			N	6	2	
AVISIT*TRTPN*PSYCHFL			Y	6	2	
AVISIT*TRTPN*PSYCHFL			N	6	3	
AVISIT*TRTPN*PSYCHFL			Y	6	3	
AVISIT*TRTPN*PSYCHFL			N	6	900	
AVISIT*TRTPN*PSYCHFL			Y	6	900	
AVISIT*TRTPN*PSYCHFL			N	10	1	1
AVISIT*TRTPN*PSYCHFL			Y	10	1	-1
AVISIT*TRTPN*PSYCHFL			N	10	2	
AVISIT*TRTPN*PSYCHFL			Y	10	2	
AVISIT*TRTPN*PSYCHFL			N	10	3	-1
AVISIT*TRTPN*PSYCHFL			Y	10	3	1
AVISIT*TRTPN*PSYCHFL			N	10	900	
AVISIT*TRTPN*PSYCHFL			Y	10	900	
AVISIT*TRTPN*PSYCHFL			N	12	1	

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*PSYCHFL			Y	12	1	
AVISIT*TRTPN*PSYCHFL			N	12	2	
AVISIT*TRTPN*PSYCHFL			Y	12	2	
AVISIT*TRTPN*PSYCHFL			N	12	3	
AVISIT*TRTPN*PSYCHFL			Y	12	3	
AVISIT*TRTPN*PSYCHFL			N	12	900	
AVISIT*TRTPN*PSYCHFL			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.6
MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY PSYCHFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

FILE: stat2f.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
PSYCHFL			N			
PSYCHFL			Y			
AVISITN*PSYCHFL			N	3		
AVISITN*PSYCHFL			Y	3		
AVISITN*PSYCHFL			N	6		
AVISITN*PSYCHFL			Y	6		
AVISITN*PSYCHFL			N	10		
AVISITN*PSYCHFL			Y	10		
AVISITN*PSYCHFL			N	12		
AVISITN*PSYCHFL			Y	12		
TRTPN*PSYCHFL			N		1	1
TRTPN*PSYCHFL			Y		1	-1
TRTPN*PSYCHFL			N		2	-1
TRTPN*PSYCHFL			Y		2	1
TRTPN*PSYCHFL			N		3	
TRTPN*PSYCHFL			Y		3	
TRTPN*PSYCHFL			N		900	

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*PSYCHFL			Y		900	
AVISIT*TRTPN*PSYCHFL			N	3	1	
AVISIT*TRTPN*PSYCHFL			Y	3	1	
AVISIT*TRTPN*PSYCHFL			N	3	2	
AVISIT*TRTPN*PSYCHFL			Y	3	2	
AVISIT*TRTPN*PSYCHFL			N	3	3	
AVISIT*TRTPN*PSYCHFL			Y	3	3	
AVISIT*TRTPN*PSYCHFL			N	3	900	
AVISIT*TRTPN*PSYCHFL			Y	3	900	
AVISIT*TRTPN*PSYCHFL			N	6	1	
AVISIT*TRTPN*PSYCHFL			Y	6	1	
AVISIT*TRTPN*PSYCHFL			N	6	2	
AVISIT*TRTPN*PSYCHFL			Y	6	2	
AVISIT*TRTPN*PSYCHFL			N	6	3	
AVISIT*TRTPN*PSYCHFL			Y	6	3	
AVISIT*TRTPN*PSYCHFL			N	6	900	
AVISIT*TRTPN*PSYCHFL			Y	6	900	
AVISIT*TRTPN*PSYCHFL			N	10	1	1

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*PSYCHFL			Y	10	1	-1
AVISIT*TRTPN*PSYCHFL			N	10	2	-1
AVISIT*TRTPN*PSYCHFL			Y	10	2	1
AVISIT*TRTPN*PSYCHFL			N	10	3	
AVISIT*TRTPN*PSYCHFL			Y	10	3	
AVISIT*TRTPN*PSYCHFL			N	10	900	
AVISIT*TRTPN*PSYCHFL			Y	10	900	
AVISIT*TRTPN*PSYCHFL			N	12	1	
AVISIT*TRTPN*PSYCHFL			Y	12	1	
AVISIT*TRTPN*PSYCHFL			N	12	2	
AVISIT*TRTPN*PSYCHFL			Y	12	2	
AVISIT*TRTPN*PSYCHFL			N	12	3	
AVISIT*TRTPN*PSYCHFL			Y	12	3	
AVISIT*TRTPN*PSYCHFL			N	12	900	
AVISIT*TRTPN*PSYCHFL			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY PSYCHFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Coefficients for Dummy X vs. Dummy Z BY PSYCHFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						

FILE: stat2f.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY PSYCHFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
PSYCHFL			N			
PSYCHFL			Y			
AVISITN*PSYCHFL			N	3		
AVISITN*PSYCHFL			Y	3		
AVISITN*PSYCHFL			N	6		
AVISITN*PSYCHFL			Y	6		
AVISITN*PSYCHFL			N	10		

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*PSYCHFL			Y	10		
AVISITN*PSYCHFL			N	12		
AVISITN*PSYCHFL			Y	12		
TRTPN*PSYCHFL			N		1	
TRTPN*PSYCHFL			Y		1	
TRTPN*PSYCHFL			N		2	1
TRTPN*PSYCHFL			Y		2	-1
TRTPN*PSYCHFL			N		3	
TRTPN*PSYCHFL			Y		3	
TRTPN*PSYCHFL			N		900	-1
TRTPN*PSYCHFL			Y		900	1
AVISIT*TRTPN*PSYCHFL			N	3	1	
AVISIT*TRTPN*PSYCHFL			Y	3	1	
AVISIT*TRTPN*PSYCHFL			N	3	2	
AVISIT*TRTPN*PSYCHFL			Y	3	2	
AVISIT*TRTPN*PSYCHFL			N	3	3	
AVISIT*TRTPN*PSYCHFL			Y	3	3	
AVISIT*TRTPN*PSYCHFL			N	3	900	

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*PSYCHFL			Y	3	900	
AVISIT*TRTPN*PSYCHFL			N	6	1	
AVISIT*TRTPN*PSYCHFL			Y	6	1	
AVISIT*TRTPN*PSYCHFL			N	6	2	
AVISIT*TRTPN*PSYCHFL			Y	6	2	
AVISIT*TRTPN*PSYCHFL			N	6	3	
AVISIT*TRTPN*PSYCHFL			Y	6	3	
AVISIT*TRTPN*PSYCHFL			N	6	900	
AVISIT*TRTPN*PSYCHFL			Y	6	900	
AVISIT*TRTPN*PSYCHFL			N	10	1	
AVISIT*TRTPN*PSYCHFL			Y	10	1	
AVISIT*TRTPN*PSYCHFL			N	10	2	1
AVISIT*TRTPN*PSYCHFL			Y	10	2	-1
AVISIT*TRTPN*PSYCHFL			N	10	3	
AVISIT*TRTPN*PSYCHFL			Y	10	3	
AVISIT*TRTPN*PSYCHFL			N	10	900	-1
AVISIT*TRTPN*PSYCHFL			Y	10	900	1
AVISIT*TRTPN*PSYCHFL			N	12	1	

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*PSYCHFL			Y	12	1	
AVISIT*TRTPN*PSYCHFL			N	12	2	
AVISIT*TRTPN*PSYCHFL			Y	12	2	
AVISIT*TRTPN*PSYCHFL			N	12	3	
AVISIT*TRTPN*PSYCHFL			Y	12	3	
AVISIT*TRTPN*PSYCHFL			N	12	900	
AVISIT*TRTPN*PSYCHFL			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.6
MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY PSYCHFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.6
 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

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The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
PSYCHFL			N			
PSYCHFL			Y			
AVISITN*PSYCHFL			N	3		
AVISITN*PSYCHFL			Y	3		
AVISITN*PSYCHFL			N	6		
AVISITN*PSYCHFL			Y	6		
AVISITN*PSYCHFL			N	10		
AVISITN*PSYCHFL			Y	10		
AVISITN*PSYCHFL			N	12		
AVISITN*PSYCHFL			Y	12		
TRTPN*PSYCHFL			N		1	
TRTPN*PSYCHFL			Y		1	
TRTPN*PSYCHFL			N		2	
TRTPN*PSYCHFL			Y		2	
TRTPN*PSYCHFL			N		3	1
TRTPN*PSYCHFL			Y		3	-1
TRTPN*PSYCHFL			N		900	-1

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The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*PSYCHFL			Y		900	1
AVISIT*TRTPN*PSYCHFL			N	3	1	
AVISIT*TRTPN*PSYCHFL			Y	3	1	
AVISIT*TRTPN*PSYCHFL			N	3	2	
AVISIT*TRTPN*PSYCHFL			Y	3	2	
AVISIT*TRTPN*PSYCHFL			N	3	3	
AVISIT*TRTPN*PSYCHFL			Y	3	3	
AVISIT*TRTPN*PSYCHFL			N	3	900	
AVISIT*TRTPN*PSYCHFL			Y	3	900	
AVISIT*TRTPN*PSYCHFL			N	6	1	
AVISIT*TRTPN*PSYCHFL			Y	6	1	
AVISIT*TRTPN*PSYCHFL			N	6	2	
AVISIT*TRTPN*PSYCHFL			Y	6	2	
AVISIT*TRTPN*PSYCHFL			N	6	3	
AVISIT*TRTPN*PSYCHFL			Y	6	3	
AVISIT*TRTPN*PSYCHFL			N	6	900	
AVISIT*TRTPN*PSYCHFL			Y	6	900	
AVISIT*TRTPN*PSYCHFL			N	10	1	

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The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*PSYCHFL			Y	10	1	
AVISIT*TRTPN*PSYCHFL			N	10	2	
AVISIT*TRTPN*PSYCHFL			Y	10	2	
AVISIT*TRTPN*PSYCHFL			N	10	3	1
AVISIT*TRTPN*PSYCHFL			Y	10	3	-1
AVISIT*TRTPN*PSYCHFL			N	10	900	-1
AVISIT*TRTPN*PSYCHFL			Y	10	900	1
AVISIT*TRTPN*PSYCHFL			N	12	1	
AVISIT*TRTPN*PSYCHFL			Y	12	1	
AVISIT*TRTPN*PSYCHFL			N	12	2	
AVISIT*TRTPN*PSYCHFL			Y	12	2	
AVISIT*TRTPN*PSYCHFL			N	12	3	
AVISIT*TRTPN*PSYCHFL			Y	12	3	
AVISIT*TRTPN*PSYCHFL			N	12	900	
AVISIT*TRTPN*PSYCHFL			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.6
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The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY PSYCHFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy W vs. Dummy Z BY PSYCHFL AT Phase B	1.4065	4.0198	235	0.35	0.7267
Dummy W vs. Dummy Y BY PSYCHFL AT Phase B	2.4487	4.0839	238	0.60	0.5493
Dummy W vs. Dummy X BY PSYCHFL AT Phase B	5.8348	4.2667	239	1.37	0.1728
Dummy X vs. Dummy Z BY PSYCHFL AT Phase B	-4.4283	4.2406	243	-1.04	0.2974
Dummy Y vs. Dummy Z BY PSYCHFL AT Phase B	-1.0422	4.0383	239	-0.26	0.7966

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----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*PSYCHFL	N	3	1	-6.1372	1.3503	284	-4.55	<.0001	0.05	-8.7950	-3.4795
AVISIT*TRTPN*PSYCHFL	Y	3	1	-6.9434	1.8105	286	-3.83	0.0002	0.05	-10.5071	-3.3797
AVISIT*TRTPN*PSYCHFL	N	3	2	-6.1027	1.4475	287	-4.22	<.0001	0.05	-8.9518	-3.2536
AVISIT*TRTPN*PSYCHFL	Y	3	2	-1.8493	1.8811	278	-0.98	0.3264	0.05	-5.5522	1.8536
AVISIT*TRTPN*PSYCHFL	N	3	3	-5.6929	1.4210	283	-4.01	<.0001	0.05	-8.4900	-2.8958
AVISIT*TRTPN*PSYCHFL	Y	3	3	-6.9042	1.6863	278	-4.09	<.0001	0.05	-10.2237	-3.5847
AVISIT*TRTPN*PSYCHFL	N	3	900	-6.4863	1.3364	282	-4.85	<.0001	0.05	-9.1169	-3.8557
AVISIT*TRTPN*PSYCHFL	Y	3	900	-5.6811	1.7378	278	-3.27	0.0012	0.05	-9.1020	-2.2602
AVISIT*TRTPN*PSYCHFL	N	6	1	-11.9025	1.6729	280	-7.11	<.0001	0.05	-15.1957	-8.6094
AVISIT*TRTPN*PSYCHFL	Y	6	1	-13.8684	2.1890	273	-6.34	<.0001	0.05	-18.1779	-9.5589
AVISIT*TRTPN*PSYCHFL	N	6	2	-9.8421	1.7652	289	-5.58	<.0001	0.05	-13.3164	-6.3678
AVISIT*TRTPN*PSYCHFL	Y	6	2	-4.5722	2.3491	272	-1.95	0.0526	0.05	-9.1969	0.05248
AVISIT*TRTPN*PSYCHFL	N	6	3	-9.3668	1.7605	285	-5.32	<.0001	0.05	-12.8321	-5.9015
AVISIT*TRTPN*PSYCHFL	Y	6	3	-10.0468	2.1052	271	-4.77	<.0001	0.05	-14.1914	-5.9022
AVISIT*TRTPN*PSYCHFL	N	6	900	-9.9468	1.6157	268	-6.16	<.0001	0.05	-13.1278	-6.7658
AVISIT*TRTPN*PSYCHFL	Y	6	900	-6.9034	2.1181	263	-3.26	0.0013	0.05	-11.0739	-2.7328
AVISIT*TRTPN*PSYCHFL	N	10	1	-16.1671	1.8153	252	-8.91	<.0001	0.05	-19.7421	-12.5920
AVISIT*TRTPN*PSYCHFL	Y	10	1	-16.8136	2.3126	239	-7.27	<.0001	0.05	-21.3694	-12.2578

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 MMRM Output for Test on Treatment by Psychosocial Support at Baseline Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Least Squares Means

Effect	E-TRIP Psychotherapy received Population	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*PSYCHFL	N	10	2	-14.0019	1.9371	276	-7.23	<.0001	0.05	-17.8151	-10.1886
AVISIT*TRTPN*PSYCHFL	Y	10	2	-8.8136	2.6020	259	-3.39	0.0008	0.05	-13.9374	-3.6898
AVISIT*TRTPN*PSYCHFL	N	10	3	-12.0719	1.8954	257	-6.37	<.0001	0.05	-15.8045	-8.3394
AVISIT*TRTPN*PSYCHFL	Y	10	3	-10.2698	2.2463	240	-4.57	<.0001	0.05	-14.6946	-5.8449
AVISIT*TRTPN*PSYCHFL	N	10	900	-10.7352	1.7357	243	-6.18	<.0001	0.05	-14.1542	-7.3162
AVISIT*TRTPN*PSYCHFL	Y	10	900	-9.9752	2.3036	249	-4.33	<.0001	0.05	-14.5122	-5.4383
AVISIT*TRTPN*PSYCHFL	N	12	1	-17.2254	1.9928	258	-8.64	<.0001	0.05	-21.1495	-13.3013
AVISIT*TRTPN*PSYCHFL	Y	12	1	-17.3662	2.5482	244	-6.81	<.0001	0.05	-22.3855	-12.3468
AVISIT*TRTPN*PSYCHFL	N	12	2	-12.3917	2.1219	274	-5.84	<.0001	0.05	-16.5690	-8.2145
AVISIT*TRTPN*PSYCHFL	Y	12	2	-11.7277	2.8526	261	-4.11	<.0001	0.05	-17.3448	-6.1106
AVISIT*TRTPN*PSYCHFL	N	12	3	-13.9717	2.0651	258	-6.77	<.0001	0.05	-18.0384	-9.9051
AVISIT*TRTPN*PSYCHFL	Y	12	3	-16.2002	2.4506	243	-6.61	<.0001	0.05	-21.0274	-11.3730
AVISIT*TRTPN*PSYCHFL	N	12	900	-12.1535	1.9208	252	-6.33	<.0001	0.05	-15.9363	-8.3708
AVISIT*TRTPN*PSYCHFL	Y	12	900	-10.7332	2.4790	244	-4.33	<.0001	0.05	-15.6162	-5.8502

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 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.7

MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
AVISITN	4	3 6 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	
COMBFL	2	N Y

FILE: stat2g.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.7

MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	299	

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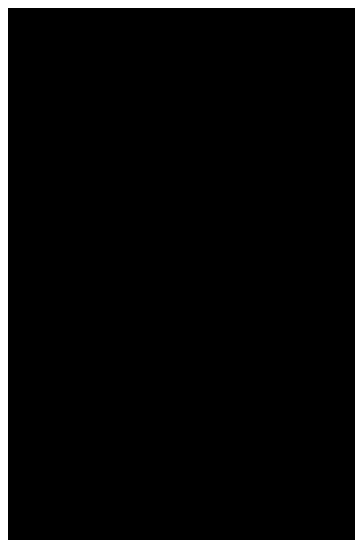
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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

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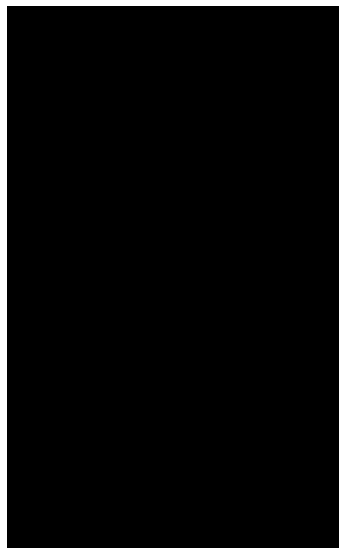
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STAT-3.7
MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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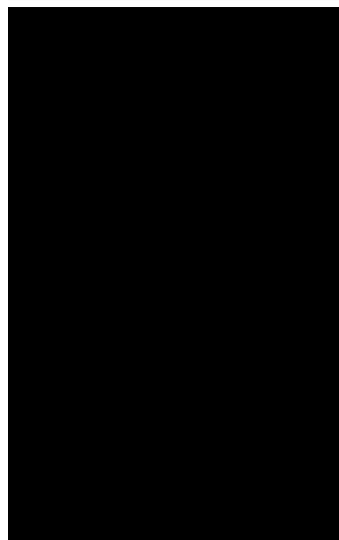
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STAT-3.7
MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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STAT-3.7
MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

PREMEDFL 2 N Y

Dimensions

Covariance Parameters	10
Columns in X	91
Columns in Z	0
Subjects	299
Max Obs per Subject	4

Number of Observations

Number of Observations Read	996
Number of Observations Used	996
Number of Observations Not Used	0

FILE: stat2g.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.7

MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	7350.10732814	
1	2	6874.16683915	0.00059842
2	1	6872.44878479	0.00002676
3	1	6872.37799072	0.00000007
4	1	6872.37782002	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	78.4556
UN(2,1)	SUBJID	53.7623
UN(2,2)	SUBJID	114.95
UN(3,1)	SUBJID	45.2487
UN(3,2)	SUBJID	91.1453
UN(3,3)	SUBJID	125.08
UN(4,1)	SUBJID	49.9731

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STAT-3.7
MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,2)	SUBJID	91.1421
UN(4,3)	SUBJID	105.71
UN(4,4)	SUBJID	148.31

Fit Statistics

-2 Res Log Likelihood	6872.4
AIC (Smaller is Better)	6892.4
AICC (Smaller is Better)	6892.6
BIC (Smaller is Better)	6929.4

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
9	477.73	<.0001

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STAT-3.7
MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
POOLCNTR	9	277	1.60	0.1137
COMBFL	1	278	4.09	0.0441
AVISITN	3	228	0.70	0.5533
TRTPN	3	263	2.90	0.0355
AVISITN*TRTPN	9	357	1.74	0.0795
PREMEDFL	1	270	1.92	0.1672
AVISITN*PREMEDFL	3	234	2.49	0.0609
TRTPN*PREMEDFL	3	265	0.15	0.9284
AVISIT*TRTPN*PREMEDF	9	357	0.57	0.8251
BASE*AVISITN	4	240	14.94	<.0001

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STAT-3.7

MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.7

MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
PREMEDFL			N			
PREMEDFL			Y			
AVISITN*PREMEDFL			N	3		
AVISITN*PREMEDFL			Y	3		
AVISITN*PREMEDFL			N	6		
AVISITN*PREMEDFL			Y	6		
AVISITN*PREMEDFL			N	10		
AVISITN*PREMEDFL			Y	10		
AVISITN*PREMEDFL			N	12		
AVISITN*PREMEDFL			Y	12		
TRTPN*PREMEDFL			N		1	1
TRTPN*PREMEDFL			Y		1	-1
TRTPN*PREMEDFL			N		2	
TRTPN*PREMEDFL			Y		2	
TRTPN*PREMEDFL			N		3	
TRTPN*PREMEDFL			Y		3	
TRTPN*PREMEDFL			N		900	-1

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STAT-3.7

MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*PREMEDFL			Y		900	1
AVISIT*TRTPN*PREMEDF			N	3	1	
AVISIT*TRTPN*PREMEDF			Y	3	1	
AVISIT*TRTPN*PREMEDF			N	3	2	
AVISIT*TRTPN*PREMEDF			Y	3	2	
AVISIT*TRTPN*PREMEDF			N	3	3	
AVISIT*TRTPN*PREMEDF			Y	3	3	
AVISIT*TRTPN*PREMEDF			N	3	900	
AVISIT*TRTPN*PREMEDF			Y	3	900	
AVISIT*TRTPN*PREMEDF			N	6	1	
AVISIT*TRTPN*PREMEDF			Y	6	1	
AVISIT*TRTPN*PREMEDF			N	6	2	
AVISIT*TRTPN*PREMEDF			Y	6	2	
AVISIT*TRTPN*PREMEDF			N	6	3	
AVISIT*TRTPN*PREMEDF			Y	6	3	
AVISIT*TRTPN*PREMEDF			N	6	900	
AVISIT*TRTPN*PREMEDF			Y	6	900	
AVISIT*TRTPN*PREMEDF			N	10	1	1

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*PREMEDF			Y	10	1	-1
AVISIT*TRTPN*PREMEDF			N	10	2	
AVISIT*TRTPN*PREMEDF			Y	10	2	
AVISIT*TRTPN*PREMEDF			N	10	3	
AVISIT*TRTPN*PREMEDF			Y	10	3	
AVISIT*TRTPN*PREMEDF			N	10	900	-1
AVISIT*TRTPN*PREMEDF			Y	10	900	1
AVISIT*TRTPN*PREMEDF			N	12	1	
AVISIT*TRTPN*PREMEDF			Y	12	1	
AVISIT*TRTPN*PREMEDF			N	12	2	
AVISIT*TRTPN*PREMEDF			Y	12	2	
AVISIT*TRTPN*PREMEDF			N	12	3	
AVISIT*TRTPN*PREMEDF			Y	12	3	
AVISIT*TRTPN*PREMEDF			N	12	900	
AVISIT*TRTPN*PREMEDF			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Coefficients for Dummy W vs. Dummy Y BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	

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STAT-3.7

MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
PREMEDFL			N			
PREMEDFL			Y			
AVISITN*PREMEDFL			N	3		
AVISITN*PREMEDFL			Y	3		
AVISITN*PREMEDFL			N	6		
AVISITN*PREMEDFL			Y	6		
AVISITN*PREMEDFL			N	10		

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*PREMEDFL			Y	10		
AVISITN*PREMEDFL			N	12		
AVISITN*PREMEDFL			Y	12		
TRTPN*PREMEDFL			N		1	1
TRTPN*PREMEDFL			Y		1	-1
TRTPN*PREMEDFL			N		2	
TRTPN*PREMEDFL			Y		2	
TRTPN*PREMEDFL			N		3	-1
TRTPN*PREMEDFL			Y		3	1
TRTPN*PREMEDFL			N		900	
TRTPN*PREMEDFL			Y		900	
AVISIT*TRTPN*PREMEDF			N	3	1	
AVISIT*TRTPN*PREMEDF			Y	3	1	
AVISIT*TRTPN*PREMEDF			N	3	2	
AVISIT*TRTPN*PREMEDF			Y	3	2	
AVISIT*TRTPN*PREMEDF			N	3	3	
AVISIT*TRTPN*PREMEDF			Y	3	3	
AVISIT*TRTPN*PREMEDF			N	3	900	

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*PREMEDF			Y	3	900	
AVISIT*TRTPN*PREMEDF			N	6	1	
AVISIT*TRTPN*PREMEDF			Y	6	1	
AVISIT*TRTPN*PREMEDF			N	6	2	
AVISIT*TRTPN*PREMEDF			Y	6	2	
AVISIT*TRTPN*PREMEDF			N	6	3	
AVISIT*TRTPN*PREMEDF			Y	6	3	
AVISIT*TRTPN*PREMEDF			N	6	900	
AVISIT*TRTPN*PREMEDF			Y	6	900	
AVISIT*TRTPN*PREMEDF			N	10	1	1
AVISIT*TRTPN*PREMEDF			Y	10	1	-1
AVISIT*TRTPN*PREMEDF			N	10	2	
AVISIT*TRTPN*PREMEDF			Y	10	2	
AVISIT*TRTPN*PREMEDF			N	10	3	-1
AVISIT*TRTPN*PREMEDF			Y	10	3	1
AVISIT*TRTPN*PREMEDF			N	10	900	
AVISIT*TRTPN*PREMEDF			Y	10	900	
AVISIT*TRTPN*PREMEDF			N	12	1	

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*PREMEDF			Y	12	1	
AVISIT*TRTPN*PREMEDF			N	12	2	
AVISIT*TRTPN*PREMEDF			Y	12	2	
AVISIT*TRTPN*PREMEDF			N	12	3	
AVISIT*TRTPN*PREMEDF			Y	12	3	
AVISIT*TRTPN*PREMEDF			N	12	900	
AVISIT*TRTPN*PREMEDF			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
PREMEDFL			N			
PREMEDFL			Y			
AVISITN*PREMEDFL			N	3		
AVISITN*PREMEDFL			Y	3		
AVISITN*PREMEDFL			N	6		
AVISITN*PREMEDFL			Y	6		
AVISITN*PREMEDFL			N	10		
AVISITN*PREMEDFL			Y	10		
AVISITN*PREMEDFL			N	12		
AVISITN*PREMEDFL			Y	12		
TRTPN*PREMEDFL			N		1	1
TRTPN*PREMEDFL			Y		1	-1
TRTPN*PREMEDFL			N		2	-1
TRTPN*PREMEDFL			Y		2	1
TRTPN*PREMEDFL			N		3	
TRTPN*PREMEDFL			Y		3	
TRTPN*PREMEDFL			N		900	

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*PREMEDFL			Y		900	
AVISIT*TRTPN*PREMEDF			N	3	1	
AVISIT*TRTPN*PREMEDF			Y	3	1	
AVISIT*TRTPN*PREMEDF			N	3	2	
AVISIT*TRTPN*PREMEDF			Y	3	2	
AVISIT*TRTPN*PREMEDF			N	3	3	
AVISIT*TRTPN*PREMEDF			Y	3	3	
AVISIT*TRTPN*PREMEDF			N	3	900	
AVISIT*TRTPN*PREMEDF			Y	3	900	
AVISIT*TRTPN*PREMEDF			N	6	1	
AVISIT*TRTPN*PREMEDF			Y	6	1	
AVISIT*TRTPN*PREMEDF			N	6	2	
AVISIT*TRTPN*PREMEDF			Y	6	2	
AVISIT*TRTPN*PREMEDF			N	6	3	
AVISIT*TRTPN*PREMEDF			Y	6	3	
AVISIT*TRTPN*PREMEDF			N	6	900	
AVISIT*TRTPN*PREMEDF			Y	6	900	
AVISIT*TRTPN*PREMEDF			N	10	1	1

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*PREMEDF			Y	10	1	-1
AVISIT*TRTPN*PREMEDF			N	10	2	-1
AVISIT*TRTPN*PREMEDF			Y	10	2	1
AVISIT*TRTPN*PREMEDF			N	10	3	
AVISIT*TRTPN*PREMEDF			Y	10	3	
AVISIT*TRTPN*PREMEDF			N	10	900	
AVISIT*TRTPN*PREMEDF			Y	10	900	
AVISIT*TRTPN*PREMEDF			N	12	1	
AVISIT*TRTPN*PREMEDF			Y	12	1	
AVISIT*TRTPN*PREMEDF			N	12	2	
AVISIT*TRTPN*PREMEDF			Y	12	2	
AVISIT*TRTPN*PREMEDF			N	12	3	
AVISIT*TRTPN*PREMEDF			Y	12	3	
AVISIT*TRTPN*PREMEDF			N	12	900	
AVISIT*TRTPN*PREMEDF			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Coefficients for Dummy X vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	

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 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
PREMEDFL			N			
PREMEDFL			Y			
AVISITN*PREMEDFL			N	3		
AVISITN*PREMEDFL			Y	3		
AVISITN*PREMEDFL			N	6		
AVISITN*PREMEDFL			Y	6		
AVISITN*PREMEDFL			N	10		

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*PREMEDFL			Y	10		
AVISITN*PREMEDFL			N	12		
AVISITN*PREMEDFL			Y	12		
TRTPN*PREMEDFL			N		1	
TRTPN*PREMEDFL			Y		1	
TRTPN*PREMEDFL			N		2	1
TRTPN*PREMEDFL			Y		2	-1
TRTPN*PREMEDFL			N		3	
TRTPN*PREMEDFL			Y		3	
TRTPN*PREMEDFL			N		900	-1
TRTPN*PREMEDFL			Y		900	1
AVISIT*TRTPN*PREMEDF			N	3	1	
AVISIT*TRTPN*PREMEDF			Y	3	1	
AVISIT*TRTPN*PREMEDF			N	3	2	
AVISIT*TRTPN*PREMEDF			Y	3	2	
AVISIT*TRTPN*PREMEDF			N	3	3	
AVISIT*TRTPN*PREMEDF			Y	3	3	
AVISIT*TRTPN*PREMEDF			N	3	900	

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*PREMEDF			Y	3	900	
AVISIT*TRTPN*PREMEDF			N	6	1	
AVISIT*TRTPN*PREMEDF			Y	6	1	
AVISIT*TRTPN*PREMEDF			N	6	2	
AVISIT*TRTPN*PREMEDF			Y	6	2	
AVISIT*TRTPN*PREMEDF			N	6	3	
AVISIT*TRTPN*PREMEDF			Y	6	3	
AVISIT*TRTPN*PREMEDF			N	6	900	
AVISIT*TRTPN*PREMEDF			Y	6	900	
AVISIT*TRTPN*PREMEDF			N	10	1	
AVISIT*TRTPN*PREMEDF			Y	10	1	
AVISIT*TRTPN*PREMEDF			N	10	2	1
AVISIT*TRTPN*PREMEDF			Y	10	2	-1
AVISIT*TRTPN*PREMEDF			N	10	3	
AVISIT*TRTPN*PREMEDF			Y	10	3	
AVISIT*TRTPN*PREMEDF			N	10	900	-1
AVISIT*TRTPN*PREMEDF			Y	10	900	1
AVISIT*TRTPN*PREMEDF			N	12	1	

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
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----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*PREMEDF			Y	12	1	
AVISIT*TRTPN*PREMEDF			N	12	2	
AVISIT*TRTPN*PREMEDF			Y	12	2	
AVISIT*TRTPN*PREMEDF			N	12	3	
AVISIT*TRTPN*PREMEDF			Y	12	3	
AVISIT*TRTPN*PREMEDF			N	12	900	
AVISIT*TRTPN*PREMEDF			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
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----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.7

MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.7

MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
PREMEDFL			N			
PREMEDFL			Y			
AVISITN*PREMEDFL			N	3		
AVISITN*PREMEDFL			Y	3		
AVISITN*PREMEDFL			N	6		
AVISITN*PREMEDFL			Y	6		
AVISITN*PREMEDFL			N	10		
AVISITN*PREMEDFL			Y	10		
AVISITN*PREMEDFL			N	12		
AVISITN*PREMEDFL			Y	12		
TRTPN*PREMEDFL			N		1	
TRTPN*PREMEDFL			Y		1	
TRTPN*PREMEDFL			N		2	
TRTPN*PREMEDFL			Y		2	
TRTPN*PREMEDFL			N		3	1
TRTPN*PREMEDFL			Y		3	-1
TRTPN*PREMEDFL			N		900	-1

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
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----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*PREMEDFL			Y		900	1
AVISIT*TRTPN*PREMEDF			N	3	1	
AVISIT*TRTPN*PREMEDF			Y	3	1	
AVISIT*TRTPN*PREMEDF			N	3	2	
AVISIT*TRTPN*PREMEDF			Y	3	2	
AVISIT*TRTPN*PREMEDF			N	3	3	
AVISIT*TRTPN*PREMEDF			Y	3	3	
AVISIT*TRTPN*PREMEDF			N	3	900	
AVISIT*TRTPN*PREMEDF			Y	3	900	
AVISIT*TRTPN*PREMEDF			N	6	1	
AVISIT*TRTPN*PREMEDF			Y	6	1	
AVISIT*TRTPN*PREMEDF			N	6	2	
AVISIT*TRTPN*PREMEDF			Y	6	2	
AVISIT*TRTPN*PREMEDF			N	6	3	
AVISIT*TRTPN*PREMEDF			Y	6	3	
AVISIT*TRTPN*PREMEDF			N	6	900	
AVISIT*TRTPN*PREMEDF			Y	6	900	
AVISIT*TRTPN*PREMEDF			N	10	1	

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STAT-3.7
 MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*PREMEDF			Y	10	1	
AVISIT*TRTPN*PREMEDF			N	10	2	
AVISIT*TRTPN*PREMEDF			Y	10	2	
AVISIT*TRTPN*PREMEDF			N	10	3	1
AVISIT*TRTPN*PREMEDF			Y	10	3	-1
AVISIT*TRTPN*PREMEDF			N	10	900	-1
AVISIT*TRTPN*PREMEDF			Y	10	900	1
AVISIT*TRTPN*PREMEDF			N	12	1	
AVISIT*TRTPN*PREMEDF			Y	12	1	
AVISIT*TRTPN*PREMEDF			N	12	2	
AVISIT*TRTPN*PREMEDF			Y	12	2	
AVISIT*TRTPN*PREMEDF			N	12	3	
AVISIT*TRTPN*PREMEDF			Y	12	3	
AVISIT*TRTPN*PREMEDF			N	12	900	
AVISIT*TRTPN*PREMEDF			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.7

MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY PREMEDFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy W vs. Dummy Z BY PREMEDFL AT Phase B	-2.5319	3.9155	241	-0.65	0.5185
Dummy W vs. Dummy Y BY PREMEDFL AT Phase B	-4.7437	3.9911	239	-1.19	0.2358
Dummy W vs. Dummy X BY PREMEDFL AT Phase B	-1.7464	4.2348	249	-0.41	0.6804
Dummy X vs. Dummy Z BY PREMEDFL AT Phase B	-0.7854	4.1316	241	-0.19	0.8494
Dummy Y vs. Dummy Z BY PREMEDFL AT Phase B	2.2118	3.8943	236	0.57	0.5706

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STAT-3.7
 MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*PREMEDF	N	3	1	-5.9586	1.4528	284	-4.10	<.0001	0.05	-8.8183	-3.0989
AVISIT*TRTPN*PREMEDF	Y	3	1	-7.1843	1.5970	284	-4.50	<.0001	0.05	-10.3277	-4.0409
AVISIT*TRTPN*PREMEDF	N	3	2	-5.3257	1.4509	286	-3.67	0.0003	0.05	-8.1813	-2.4700
AVISIT*TRTPN*PREMEDF	Y	3	2	-3.2959	1.8974	283	-1.74	0.0835	0.05	-7.0308	0.4390
AVISIT*TRTPN*PREMEDF	N	3	3	-6.0331	1.5188	280	-3.97	<.0001	0.05	-9.0227	-3.0434
AVISIT*TRTPN*PREMEDF	Y	3	3	-6.4722	1.5379	280	-4.21	<.0001	0.05	-9.4996	-3.4448
AVISIT*TRTPN*PREMEDF	N	3	900	-5.2659	1.4825	280	-3.55	0.0004	0.05	-8.1842	-2.3476
AVISIT*TRTPN*PREMEDF	Y	3	900	-7.3272	1.5014	280	-4.88	<.0001	0.05	-10.2826	-4.3718
AVISIT*TRTPN*PREMEDF	N	6	1	-13.5175	1.8602	291	-7.27	<.0001	0.05	-17.1786	-9.8564
AVISIT*TRTPN*PREMEDF	Y	6	1	-11.8145	1.9044	255	-6.20	<.0001	0.05	-15.5649	-8.0641
AVISIT*TRTPN*PREMEDF	N	6	2	-8.2573	1.7743	290	-4.65	<.0001	0.05	-11.7494	-4.7652
AVISIT*TRTPN*PREMEDF	Y	6	2	-7.6094	2.3669	273	-3.21	0.0015	0.05	-12.2690	-2.9498
AVISIT*TRTPN*PREMEDF	N	6	3	-10.1851	1.9237	278	-5.29	<.0001	0.05	-13.9719	-6.3982
AVISIT*TRTPN*PREMEDF	Y	6	3	-9.2714	1.9102	274	-4.85	<.0001	0.05	-13.0318	-5.5109
AVISIT*TRTPN*PREMEDF	N	6	900	-9.2920	1.8273	271	-5.09	<.0001	0.05	-12.8895	-5.6945
AVISIT*TRTPN*PREMEDF	Y	6	900	-8.5329	1.8245	258	-4.68	<.0001	0.05	-12.1258	-4.9401
AVISIT*TRTPN*PREMEDF	N	10	1	-19.0715	1.9707	256	-9.68	<.0001	0.05	-22.9524	-15.1906
AVISIT*TRTPN*PREMEDF	Y	10	1	-13.6610	2.0425	237	-6.69	<.0001	0.05	-17.6847	-9.6373

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MMRM Output for Test on Treatment by Previous Pharmacological Treatment Intervention for PTSD Interaction
 (Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Least Squares Means

Effect	E-TRIP Prescription Medication Usage Pop	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*PREMEDF	N	10	2	-13.5968	1.9479	284	-6.98	<.0001	0.05	-17.4309	-9.7628
AVISIT*TRTPN*PREMEDF	Y	10	2	-9.9327	2.5490	250	-3.90	0.0001	0.05	-14.9529	-4.9125
AVISIT*TRTPN*PREMEDF	N	10	3	-11.7285	2.0469	249	-5.73	<.0001	0.05	-15.7598	-7.6971
AVISIT*TRTPN*PREMEDF	Y	10	3	-11.0617	2.0291	245	-5.45	<.0001	0.05	-15.0583	-7.0650
AVISIT*TRTPN*PREMEDF	N	10	900	-11.9431	1.9566	251	-6.10	<.0001	0.05	-15.7965	-8.0897
AVISIT*TRTPN*PREMEDF	Y	10	900	-9.0645	1.9476	239	-4.65	<.0001	0.05	-12.9011	-5.2278
AVISIT*TRTPN*PREMEDF	N	12	1	-19.5557	2.1581	261	-9.06	<.0001	0.05	-23.8051	-15.3062
AVISIT*TRTPN*PREMEDF	Y	12	1	-14.9362	2.2502	242	-6.64	<.0001	0.05	-19.3687	-10.5036
AVISIT*TRTPN*PREMEDF	N	12	2	-12.8805	2.1286	280	-6.05	<.0001	0.05	-17.0706	-8.6903
AVISIT*TRTPN*PREMEDF	Y	12	2	-11.1719	2.7840	249	-4.01	<.0001	0.05	-16.6550	-5.6887
AVISIT*TRTPN*PREMEDF	N	12	3	-15.7175	2.2111	244	-7.11	<.0001	0.05	-20.0728	-11.3622
AVISIT*TRTPN*PREMEDF	Y	12	3	-14.1342	2.2280	250	-6.34	<.0001	0.05	-18.5223	-9.7462
AVISIT*TRTPN*PREMEDF	N	12	900	-13.1450	2.1214	247	-6.20	<.0001	0.05	-17.3234	-8.9666
AVISIT*TRTPN*PREMEDF	Y	12	900	-10.2577	2.1553	249	-4.76	<.0001	0.05	-14.5028	-6.0127

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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
AVISITN	4	3 6 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	[REDACTED]
COMBFL	2	N Y

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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	299	

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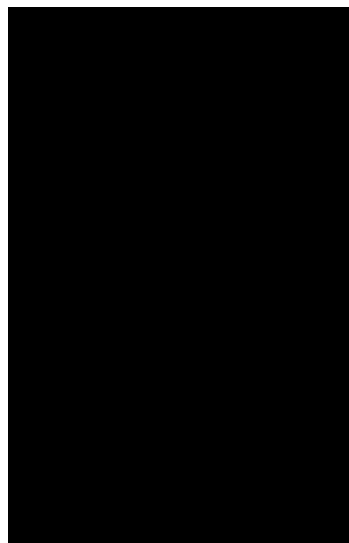
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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction
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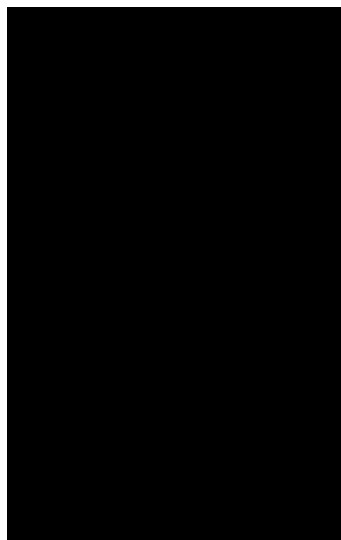
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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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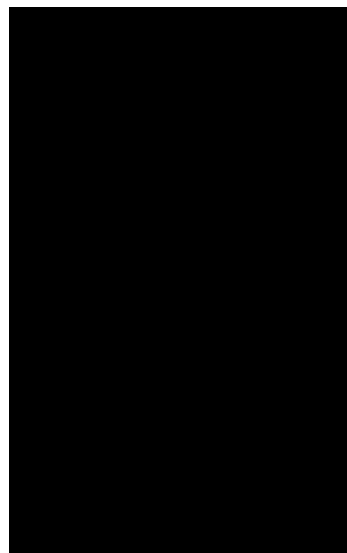
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MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

ACTFL 2 N Y

Dimensions

Covariance Parameters	10
Columns in X	91
Columns in Z	0
Subjects	299
Max Obs per Subject	4

Number of Observations

Number of Observations Read	996
Number of Observations Used	996
Number of Observations Not Used	0

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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	7339.70119712	
1	2	6874.98262651	0.00097377
2	1	6872.12913247	0.00006613
3	1	6871.95142830	0.00000039
4	1	6871.95041291	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	78.9311
UN(2,1)	SUBJID	53.3500
UN(2,2)	SUBJID	114.65
UN(3,1)	SUBJID	44.7163
UN(3,2)	SUBJID	90.3579
UN(3,3)	SUBJID	125.18
UN(4,1)	SUBJID	48.5868

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MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,2)	SUBJID	89.8766
UN(4,3)	SUBJID	104.28
UN(4,4)	SUBJID	144.74

Fit Statistics

-2 Res Log Likelihood	6872.0
AIC (Smaller is Better)	6892.0
AICC (Smaller is Better)	6892.2
BIC (Smaller is Better)	6929.0

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
9	467.75	<.0001

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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
POOLCNTR	9	277	1.68	0.0946
COMBFL	1	278	3.85	0.0508
AVISITN	3	226	0.76	0.5187
TRTPN	3	270	2.10	0.1003
AVISITN*TRTPN	9	361	1.02	0.4226
ACTFL	1	298	2.40	0.1224
AVISITN*ACTFL	3	235	2.48	0.0619
TRTPN*ACTFL	3	271	0.04	0.9904
AVISITN*TRTPN*ACTFL	9	361	0.32	0.9679
BASE*AVISITN	4	240	13.44	<.0001

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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
ACTFL			N			
ACTFL			Y			
AVISITN*ACTFL			N	3		
AVISITN*ACTFL			Y	3		
AVISITN*ACTFL			N	6		
AVISITN*ACTFL			Y	6		
AVISITN*ACTFL			N	10		
AVISITN*ACTFL			Y	10		
AVISITN*ACTFL			N	12		
AVISITN*ACTFL			Y	12		
TRTPN*ACTFL			N		1	1
TRTPN*ACTFL			Y		1	-1
TRTPN*ACTFL			N		2	
TRTPN*ACTFL			Y		2	
TRTPN*ACTFL			N		3	
TRTPN*ACTFL			Y		3	
TRTPN*ACTFL			N		900	-1

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*ACTFL			Y		900	1
AVISITN*TRTPN*ACTFL			N	3	1	
AVISITN*TRTPN*ACTFL			Y	3	1	
AVISITN*TRTPN*ACTFL			N	3	2	
AVISITN*TRTPN*ACTFL			Y	3	2	
AVISITN*TRTPN*ACTFL			N	3	3	
AVISITN*TRTPN*ACTFL			Y	3	3	
AVISITN*TRTPN*ACTFL			N	3	900	
AVISITN*TRTPN*ACTFL			Y	3	900	
AVISITN*TRTPN*ACTFL			N	6	1	
AVISITN*TRTPN*ACTFL			Y	6	1	
AVISITN*TRTPN*ACTFL			N	6	2	
AVISITN*TRTPN*ACTFL			Y	6	2	
AVISITN*TRTPN*ACTFL			N	6	3	
AVISITN*TRTPN*ACTFL			Y	6	3	
AVISITN*TRTPN*ACTFL			N	6	900	
AVISITN*TRTPN*ACTFL			Y	6	900	
AVISITN*TRTPN*ACTFL			N	10	1	1

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*ACTFL			Y	10	1	-1
AVISITN*TRTPN*ACTFL			N	10	2	
AVISITN*TRTPN*ACTFL			Y	10	2	
AVISITN*TRTPN*ACTFL			N	10	3	
AVISITN*TRTPN*ACTFL			Y	10	3	
AVISITN*TRTPN*ACTFL			N	10	900	-1
AVISITN*TRTPN*ACTFL			Y	10	900	1
AVISITN*TRTPN*ACTFL			N	12	1	
AVISITN*TRTPN*ACTFL			Y	12	1	
AVISITN*TRTPN*ACTFL			N	12	2	
AVISITN*TRTPN*ACTFL			Y	12	2	
AVISITN*TRTPN*ACTFL			N	12	3	
AVISITN*TRTPN*ACTFL			Y	12	3	
AVISITN*TRTPN*ACTFL			N	12	900	
AVISITN*TRTPN*ACTFL			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Coefficients for Dummy W vs. Dummy Y BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
ACTFL			N			
ACTFL			Y			
AVISITN*ACTFL			N	3		
AVISITN*ACTFL			Y	3		
AVISITN*ACTFL			N	6		
AVISITN*ACTFL			Y	6		
AVISITN*ACTFL			N	10		

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*ACTFL			Y	10		
AVISITN*ACTFL			N	12		
AVISITN*ACTFL			Y	12		
TRTPN*ACTFL			N		1	1
TRTPN*ACTFL			Y		1	-1
TRTPN*ACTFL			N		2	
TRTPN*ACTFL			Y		2	
TRTPN*ACTFL			N		3	-1
TRTPN*ACTFL			Y		3	1
TRTPN*ACTFL			N		900	
TRTPN*ACTFL			Y		900	
AVISITN*TRTPN*ACTFL			N	3	1	
AVISITN*TRTPN*ACTFL			Y	3	1	
AVISITN*TRTPN*ACTFL			N	3	2	
AVISITN*TRTPN*ACTFL			Y	3	2	
AVISITN*TRTPN*ACTFL			N	3	3	
AVISITN*TRTPN*ACTFL			Y	3	3	
AVISITN*TRTPN*ACTFL			N	3	900	

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*ACTFL			Y	3	900	
AVISITN*TRTPN*ACTFL			N	6	1	
AVISITN*TRTPN*ACTFL			Y	6	1	
AVISITN*TRTPN*ACTFL			N	6	2	
AVISITN*TRTPN*ACTFL			Y	6	2	
AVISITN*TRTPN*ACTFL			N	6	3	
AVISITN*TRTPN*ACTFL			Y	6	3	
AVISITN*TRTPN*ACTFL			N	6	900	
AVISITN*TRTPN*ACTFL			Y	6	900	
AVISITN*TRTPN*ACTFL			N	10	1	1
AVISITN*TRTPN*ACTFL			Y	10	1	-1
AVISITN*TRTPN*ACTFL			N	10	2	
AVISITN*TRTPN*ACTFL			Y	10	2	
AVISITN*TRTPN*ACTFL			N	10	3	-1
AVISITN*TRTPN*ACTFL			Y	10	3	1
AVISITN*TRTPN*ACTFL			N	10	900	
AVISITN*TRTPN*ACTFL			Y	10	900	
AVISITN*TRTPN*ACTFL			N	12	1	

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy Y BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*ACTFL			Y	12	1	
AVISITN*TRTPN*ACTFL			N	12	2	
AVISITN*TRTPN*ACTFL			Y	12	2	
AVISITN*TRTPN*ACTFL			N	12	3	
AVISITN*TRTPN*ACTFL			Y	12	3	
AVISITN*TRTPN*ACTFL			N	12	900	
AVISITN*TRTPN*ACTFL			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
ACTFL			N			
ACTFL			Y			
AVISITN*ACTFL			N	3		
AVISITN*ACTFL			Y	3		
AVISITN*ACTFL			N	6		
AVISITN*ACTFL			Y	6		
AVISITN*ACTFL			N	10		
AVISITN*ACTFL			Y	10		
AVISITN*ACTFL			N	12		
AVISITN*ACTFL			Y	12		
TRTPN*ACTFL			N		1	1
TRTPN*ACTFL			Y		1	-1
TRTPN*ACTFL			N		2	-1
TRTPN*ACTFL			Y		2	1
TRTPN*ACTFL			N		3	
TRTPN*ACTFL			Y		3	
TRTPN*ACTFL			N		900	

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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*ACTFL			Y		900	
AVISITN*TRTPN*ACTFL			N	3	1	
AVISITN*TRTPN*ACTFL			Y	3	1	
AVISITN*TRTPN*ACTFL			N	3	2	
AVISITN*TRTPN*ACTFL			Y	3	2	
AVISITN*TRTPN*ACTFL			N	3	3	
AVISITN*TRTPN*ACTFL			Y	3	3	
AVISITN*TRTPN*ACTFL			N	3	900	
AVISITN*TRTPN*ACTFL			Y	3	900	
AVISITN*TRTPN*ACTFL			N	6	1	
AVISITN*TRTPN*ACTFL			Y	6	1	
AVISITN*TRTPN*ACTFL			N	6	2	
AVISITN*TRTPN*ACTFL			Y	6	2	
AVISITN*TRTPN*ACTFL			N	6	3	
AVISITN*TRTPN*ACTFL			Y	6	3	
AVISITN*TRTPN*ACTFL			N	6	900	
AVISITN*TRTPN*ACTFL			Y	6	900	
AVISITN*TRTPN*ACTFL			N	10	1	1

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*ACTFL			Y	10	1	-1
AVISITN*TRTPN*ACTFL			N	10	2	-1
AVISITN*TRTPN*ACTFL			Y	10	2	1
AVISITN*TRTPN*ACTFL			N	10	3	
AVISITN*TRTPN*ACTFL			Y	10	3	
AVISITN*TRTPN*ACTFL			N	10	900	
AVISITN*TRTPN*ACTFL			Y	10	900	
AVISITN*TRTPN*ACTFL			N	12	1	
AVISITN*TRTPN*ACTFL			Y	12	1	
AVISITN*TRTPN*ACTFL			N	12	2	
AVISITN*TRTPN*ACTFL			Y	12	2	
AVISITN*TRTPN*ACTFL			N	12	3	
AVISITN*TRTPN*ACTFL			Y	12	3	
AVISITN*TRTPN*ACTFL			N	12	900	
AVISITN*TRTPN*ACTFL			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs. Dummy X BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Coefficients for Dummy X vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					

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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	
AVISITN*TRTPN				12	900	
ACTFL			N			
ACTFL			Y			
AVISITN*ACTFL			N	3		
AVISITN*ACTFL			Y	3		
AVISITN*ACTFL			N	6		
AVISITN*ACTFL			Y	6		
AVISITN*ACTFL			N	10		

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*ACTFL			Y	10		
AVISITN*ACTFL			N	12		
AVISITN*ACTFL			Y	12		
TRTPN*ACTFL			N		1	
TRTPN*ACTFL			Y		1	
TRTPN*ACTFL			N		2	1
TRTPN*ACTFL			Y		2	-1
TRTPN*ACTFL			N		3	
TRTPN*ACTFL			Y		3	
TRTPN*ACTFL			N		900	-1
TRTPN*ACTFL			Y		900	1
AVISITN*TRTPN*ACTFL			N	3	1	
AVISITN*TRTPN*ACTFL			Y	3	1	
AVISITN*TRTPN*ACTFL			N	3	2	
AVISITN*TRTPN*ACTFL			Y	3	2	
AVISITN*TRTPN*ACTFL			N	3	3	
AVISITN*TRTPN*ACTFL			Y	3	3	
AVISITN*TRTPN*ACTFL			N	3	900	

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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*ACTFL			Y	3	900	
AVISITN*TRTPN*ACTFL			N	6	1	
AVISITN*TRTPN*ACTFL			Y	6	1	
AVISITN*TRTPN*ACTFL			N	6	2	
AVISITN*TRTPN*ACTFL			Y	6	2	
AVISITN*TRTPN*ACTFL			N	6	3	
AVISITN*TRTPN*ACTFL			Y	6	3	
AVISITN*TRTPN*ACTFL			N	6	900	
AVISITN*TRTPN*ACTFL			Y	6	900	
AVISITN*TRTPN*ACTFL			N	10	1	
AVISITN*TRTPN*ACTFL			Y	10	1	
AVISITN*TRTPN*ACTFL			N	10	2	1
AVISITN*TRTPN*ACTFL			Y	10	2	-1
AVISITN*TRTPN*ACTFL			N	10	3	
AVISITN*TRTPN*ACTFL			Y	10	3	
AVISITN*TRTPN*ACTFL			N	10	900	-1
AVISITN*TRTPN*ACTFL			Y	10	900	1
AVISITN*TRTPN*ACTFL			N	12	1	

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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*ACTFL			Y	12	1	
AVISITN*TRTPN*ACTFL			N	12	2	
AVISITN*TRTPN*ACTFL			Y	12	2	
AVISITN*TRTPN*ACTFL			N	12	3	
AVISITN*TRTPN*ACTFL			Y	12	3	
AVISITN*TRTPN*ACTFL			N	12	900	
AVISITN*TRTPN*ACTFL			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
ACTFL			N			
ACTFL			Y			
AVISITN*ACTFL			N	3		
AVISITN*ACTFL			Y	3		
AVISITN*ACTFL			N	6		
AVISITN*ACTFL			Y	6		
AVISITN*ACTFL			N	10		
AVISITN*ACTFL			Y	10		
AVISITN*ACTFL			N	12		
AVISITN*ACTFL			Y	12		
TRTPN*ACTFL			N		1	
TRTPN*ACTFL			Y		1	
TRTPN*ACTFL			N		2	
TRTPN*ACTFL			Y		2	
TRTPN*ACTFL			N		3	1
TRTPN*ACTFL			Y		3	-1
TRTPN*ACTFL			N		900	-1

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STAT-3.8
MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*ACTFL			Y		900	1
AVISITN*TRTPN*ACTFL			N	3	1	
AVISITN*TRTPN*ACTFL			Y	3	1	
AVISITN*TRTPN*ACTFL			N	3	2	
AVISITN*TRTPN*ACTFL			Y	3	2	
AVISITN*TRTPN*ACTFL			N	3	3	
AVISITN*TRTPN*ACTFL			Y	3	3	
AVISITN*TRTPN*ACTFL			N	3	900	
AVISITN*TRTPN*ACTFL			Y	3	900	
AVISITN*TRTPN*ACTFL			N	6	1	
AVISITN*TRTPN*ACTFL			Y	6	1	
AVISITN*TRTPN*ACTFL			N	6	2	
AVISITN*TRTPN*ACTFL			Y	6	2	
AVISITN*TRTPN*ACTFL			N	6	3	
AVISITN*TRTPN*ACTFL			Y	6	3	
AVISITN*TRTPN*ACTFL			N	6	900	
AVISITN*TRTPN*ACTFL			Y	6	900	
AVISITN*TRTPN*ACTFL			N	10	1	

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY ACTFL AT Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN*ACTFL			Y	10	1	
AVISITN*TRTPN*ACTFL			N	10	2	
AVISITN*TRTPN*ACTFL			Y	10	2	
AVISITN*TRTPN*ACTFL			N	10	3	1
AVISITN*TRTPN*ACTFL			Y	10	3	-1
AVISITN*TRTPN*ACTFL			N	10	900	-1
AVISITN*TRTPN*ACTFL			Y	10	900	1
AVISITN*TRTPN*ACTFL			N	12	1	
AVISITN*TRTPN*ACTFL			Y	12	1	
AVISITN*TRTPN*ACTFL			N	12	2	
AVISITN*TRTPN*ACTFL			Y	12	2	
AVISITN*TRTPN*ACTFL			N	12	3	
AVISITN*TRTPN*ACTFL			Y	12	3	
AVISITN*TRTPN*ACTFL			N	12	900	
AVISITN*TRTPN*ACTFL			Y	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		

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 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs. Dummy Z BY ACTFL AT Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Row1
BASE*AVISITN				12		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy W vs. Dummy Z BY ACTFL AT Phase B	1.7942	4.5698	247	0.39	0.6949
Dummy W vs. Dummy Y BY ACTFL AT Phase B	2.8032	4.5573	240	0.62	0.5391
Dummy W vs. Dummy X BY ACTFL AT Phase B	0.8858	4.6363	246	0.19	0.8486
Dummy X vs. Dummy Z BY ACTFL AT Phase B	0.9084	4.4137	246	0.21	0.8371
Dummy Y vs. Dummy Z BY ACTFL AT Phase B	-1.0090	4.3555	241	-0.23	0.8170

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN*ACTFL	N	3	1	-7.9435	2.1206	284	-3.75	0.0002	0.05	-12.1176	-3.7693
AVISITN*TRTPN*ACTFL	Y	3	1	-5.9863	1.2849	286	-4.66	<.0001	0.05	-8.5154	-3.4573
AVISITN*TRTPN*ACTFL	N	3	2	-3.5042	2.0389	284	-1.72	0.0868	0.05	-7.5174	0.5090
AVISITN*TRTPN*ACTFL	Y	3	2	-5.1180	1.4112	286	-3.63	0.0003	0.05	-7.8956	-2.3404
AVISITN*TRTPN*ACTFL	N	3	3	-5.6913	1.9165	277	-2.97	0.0032	0.05	-9.4641	-1.9186
AVISITN*TRTPN*ACTFL	Y	3	3	-6.4961	1.3592	284	-4.78	<.0001	0.05	-9.1715	-3.8208
AVISITN*TRTPN*ACTFL	N	3	900	-5.4811	1.9443	279	-2.82	0.0052	0.05	-9.3084	-1.6537
AVISITN*TRTPN*ACTFL	Y	3	900	-6.5675	1.2908	282	-5.09	<.0001	0.05	-9.1084	-4.0266
AVISITN*TRTPN*ACTFL	N	6	1	-11.9700	2.7777	291	-4.31	<.0001	0.05	-17.4369	-6.5032
AVISITN*TRTPN*ACTFL	Y	6	1	-12.8305	1.5449	272	-8.30	<.0001	0.05	-15.8720	-9.7890
AVISITN*TRTPN*ACTFL	N	6	2	-7.4242	2.4665	274	-3.01	0.0029	0.05	-12.2798	-2.5685
AVISITN*TRTPN*ACTFL	Y	6	2	-8.2664	1.7407	287	-4.75	<.0001	0.05	-11.6924	-4.8404
AVISITN*TRTPN*ACTFL	N	6	3	-9.0108	2.4003	265	-3.75	0.0002	0.05	-13.7369	-4.2847
AVISITN*TRTPN*ACTFL	Y	6	3	-10.0441	1.6821	292	-5.97	<.0001	0.05	-13.3547	-6.7336
AVISITN*TRTPN*ACTFL	N	6	900	-7.2664	2.3780	263	-3.06	0.0025	0.05	-11.9489	-2.5840
AVISITN*TRTPN*ACTFL	Y	6	900	-9.5807	1.5605	272	-6.14	<.0001	0.05	-12.6530	-6.5085
AVISITN*TRTPN*ACTFL	N	10	1	-13.4038	3.0528	264	-4.39	<.0001	0.05	-19.4147	-7.3929
AVISITN*TRTPN*ACTFL	Y	10	1	-17.2135	1.6338	245	-10.54	<.0001	0.05	-20.4316	-13.9953

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STAT-3.8
 MMRM Output for Test on Treatment by Use of Wearable Device Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	Actiwatch Usage Population Flag	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN*ACTFL	N	10	2	-10.2150	2.6569	254	-3.84	0.0002	0.05	-15.4473	-4.9826
AVISITN*TRTPN*ACTFL	Y	10	2	-13.1389	1.9171	279	-6.85	<.0001	0.05	-16.9128	-9.3650
AVISITN*TRTPN*ACTFL	N	10	3	-10.7035	2.6193	247	-4.09	<.0001	0.05	-15.8625	-5.5445
AVISITN*TRTPN*ACTFL	Y	10	3	-11.7100	1.7693	256	-6.62	<.0001	0.05	-15.1942	-8.2258
AVISITN*TRTPN*ACTFL	N	10	900	-9.0686	2.6623	264	-3.41	0.0008	0.05	-14.3107	-3.8266
AVISITN*TRTPN*ACTFL	Y	10	900	-11.0841	1.6435	245	-6.74	<.0001	0.05	-14.3214	-7.8469
AVISITN*TRTPN*ACTFL	N	12	1	-13.8921	3.2980	265	-4.21	<.0001	0.05	-20.3857	-7.3986
AVISITN*TRTPN*ACTFL	Y	12	1	-18.1845	1.7699	254	-10.27	<.0001	0.05	-21.6699	-14.6990
AVISITN*TRTPN*ACTFL	N	12	2	-8.4998	2.9027	263	-2.93	0.0037	0.05	-14.2153	-2.7843
AVISITN*TRTPN*ACTFL	Y	12	2	-14.0508	2.0523	275	-6.85	<.0001	0.05	-18.0910	-10.0107
AVISITN*TRTPN*ACTFL	N	12	3	-11.9079	2.8635	255	-4.16	<.0001	0.05	-17.5471	-6.2687
AVISITN*TRTPN*ACTFL	Y	12	3	-16.1860	1.8861	256	-8.58	<.0001	0.05	-19.9002	-12.4718
AVISITN*TRTPN*ACTFL	N	12	900	-8.6752	2.8453	262	-3.05	0.0025	0.05	-14.2778	-3.0727
AVISITN*TRTPN*ACTFL	Y	12	900	-12.8390	1.7772	252	-7.22	<.0001	0.05	-16.3390	-9.3390

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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
AVISITN	4	3 6 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	
COMBFL	2	N Y

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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	297	

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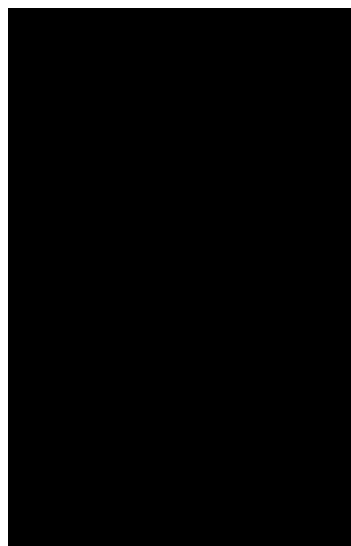
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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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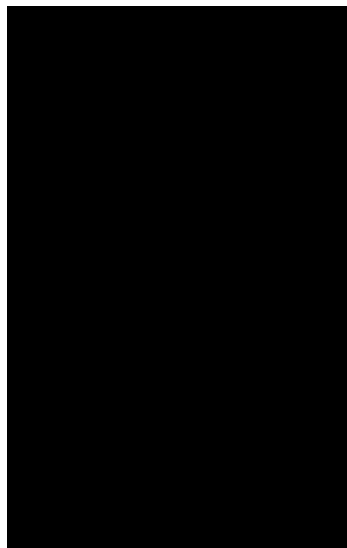
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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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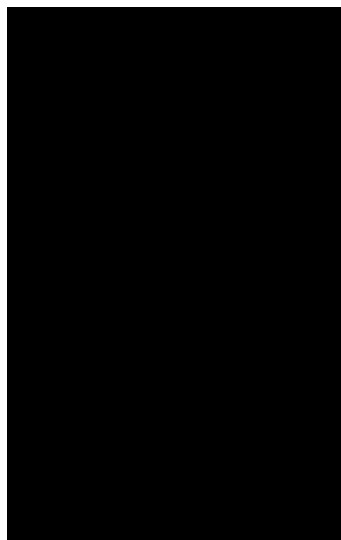
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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

IEDURGRP 3 IEDURGRP1: <5 IEDURGRP2: >=5 -
<10 IEDURGRP3: >=10

Dimensions

Covariance Parameters	10
Columns in X	116
Columns in Z	0
Subjects	297
Max Obs per Subject	4

Number of Observations

Number of Observations Read	996
Number of Observations Used	988
Number of Observations Not Used	8

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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	7181.92830375	
1	2	6732.11084333	0.00081044
2	1	6729.79975003	0.00004736
3	1	6729.67570335	0.00000021
4	1	6729.67518003	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	77.3339
UN(2,1)	SUBJID	53.4661
UN(2,2)	SUBJID	115.65
UN(3,1)	SUBJID	42.3834
UN(3,2)	SUBJID	89.8338
UN(3,3)	SUBJID	121.60
UN(4,1)	SUBJID	46.9018

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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,2)	SUBJID	89.8566
UN(4,3)	SUBJID	101.45
UN(4,4)	SUBJID	143.37

Fit Statistics

-2 Res Log Likelihood	6729.7
AIC (Smaller is Better)	6749.7
AICC (Smaller is Better)	6749.9
BIC (Smaller is Better)	6786.6

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
9	452.25	<.0001

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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
POOLCNTR	9	270	2.05	0.0345
COMBFL	1	273	4.81	0.0291
AVISITN	3	222	0.64	0.5878
TRTPN	3	258	2.96	0.0327
AVISITN*TRTPN	9	351	1.90	0.0511
IEDURGRP	2	267	1.39	0.2521
AVISITN*IEDURGRP	6	301	2.13	0.0500
TRTPN*IEDURGRP	6	260	1.21	0.2989
AVISIT*TRTPN*IEDURGR	18	437	1.04	0.4164
BASE*AVISITN	4	235	13.86	<.0001

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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
IEDURGRP			IEDURGRP1: <5			
IEDURGRP			IEDURGRP2: >=5 - <10			
IEDURGRP			IEDURGRP3: >=10			
AVISITN*IEDURGRP			IEDURGRP1: <5	3		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	3		
AVISITN*IEDURGRP			IEDURGRP3: >=10	3		
AVISITN*IEDURGRP			IEDURGRP1: <5	6		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	6		
AVISITN*IEDURGRP			IEDURGRP3: >=10	6		
AVISITN*IEDURGRP			IEDURGRP1: <5	10		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	10		
AVISITN*IEDURGRP			IEDURGRP3: >=10	10		
AVISITN*IEDURGRP			IEDURGRP1: <5	12		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	12		
AVISITN*IEDURGRP			IEDURGRP3: >=10	12		
TRTPN*IEDURGRP			IEDURGRP1: <5		1	1
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		1	-1

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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*IEDURGRP			IEDURGRP3: >=10		1	
TRTPN*IEDURGRP			IEDURGRP1: <5		2	
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		2	
TRTPN*IEDURGRP			IEDURGRP3: >=10		2	
TRTPN*IEDURGRP			IEDURGRP1: <5		3	
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		3	
TRTPN*IEDURGRP			IEDURGRP3: >=10		3	
TRTPN*IEDURGRP			IEDURGRP1: <5		900	-1
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		900	1
TRTPN*IEDURGRP			IEDURGRP3: >=10		900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	3	

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 PROGRAM: /opt/sas/Data/DAF/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	1	1
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	1	-1

FILE: stat2i.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	900	-1
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	900	1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	3	

FILE: stat2i.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

FILE: stat2i.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
IEDURGRP			IEDURGRP1: <5			
IEDURGRP			IEDURGRP2: >=5 - <10			
IEDURGRP			IEDURGRP3: >=10			
AVISITN*IEDURGRP			IEDURGRP1: <5	3		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	3		
AVISITN*IEDURGRP			IEDURGRP3: >=10	3		
AVISITN*IEDURGRP			IEDURGRP1: <5	6		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	6		
AVISITN*IEDURGRP			IEDURGRP3: >=10	6		
AVISITN*IEDURGRP			IEDURGRP1: <5	10		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	10		
AVISITN*IEDURGRP			IEDURGRP3: >=10	10		
AVISITN*IEDURGRP			IEDURGRP1: <5	12		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	12		
AVISITN*IEDURGRP			IEDURGRP3: >=10	12		
TRTPN*IEDURGRP			IEDURGRP1: <5		1	1
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		1	-1

FILE: stat2i.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*IEDURGRP			IEDURGRP3: >=10		1	
TRTPN*IEDURGRP			IEDURGRP1: <5		2	
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		2	
TRTPN*IEDURGRP			IEDURGRP3: >=10		2	
TRTPN*IEDURGRP			IEDURGRP1: <5		3	-1
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		3	1
TRTPN*IEDURGRP			IEDURGRP3: >=10		3	
TRTPN*IEDURGRP			IEDURGRP1: <5		900	
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		900	
TRTPN*IEDURGRP			IEDURGRP3: >=10		900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	3	

FILE: stat2i.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	1	1
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	1	-1

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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	3	-1
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	3	1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	3	

FILE: stat2i.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAF/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
IEDURGRP			IEDURGRP1: <5			
IEDURGRP			IEDURGRP2: >=5 - <10			
IEDURGRP			IEDURGRP3: >=10			
AVISITN*IEDURGRP			IEDURGRP1: <5	3		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	3		
AVISITN*IEDURGRP			IEDURGRP3: >=10	3		
AVISITN*IEDURGRP			IEDURGRP1: <5	6		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	6		
AVISITN*IEDURGRP			IEDURGRP3: >=10	6		
AVISITN*IEDURGRP			IEDURGRP1: <5	10		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	10		
AVISITN*IEDURGRP			IEDURGRP3: >=10	10		
AVISITN*IEDURGRP			IEDURGRP1: <5	12		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	12		
AVISITN*IEDURGRP			IEDURGRP3: >=10	12		
TRTPN*IEDURGRP			IEDURGRP1: <5		1	1
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		1	-1

FILE: stat2i.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*IEDURGRP			IEDURGRP3: >=10		1	
TRTPN*IEDURGRP			IEDURGRP1: <5		2	-1
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		2	1
TRTPN*IEDURGRP			IEDURGRP3: >=10		2	
TRTPN*IEDURGRP			IEDURGRP1: <5		3	
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		3	
TRTPN*IEDURGRP			IEDURGRP3: >=10		3	
TRTPN*IEDURGRP			IEDURGRP1: <5		900	
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		900	
TRTPN*IEDURGRP			IEDURGRP3: >=10		900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	3	

FILE: stat2i.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	1	1
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	1	-1

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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	2	-1
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	2	1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	3	

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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
IEDURGRP			IEDURGRP1: <5			
IEDURGRP			IEDURGRP2: >=5 - <10			
IEDURGRP			IEDURGRP3: >=10			
AVISITN*IEDURGRP			IEDURGRP1: <5	3		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	3		
AVISITN*IEDURGRP			IEDURGRP3: >=10	3		
AVISITN*IEDURGRP			IEDURGRP1: <5	6		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	6		
AVISITN*IEDURGRP			IEDURGRP3: >=10	6		
AVISITN*IEDURGRP			IEDURGRP1: <5	10		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	10		
AVISITN*IEDURGRP			IEDURGRP3: >=10	10		
AVISITN*IEDURGRP			IEDURGRP1: <5	12		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	12		
AVISITN*IEDURGRP			IEDURGRP3: >=10	12		
TRTPN*IEDURGRP			IEDURGRP1: <5		1	
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		1	

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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*IEDURGRP			IEDURGRP3: >=10		1	
TRTPN*IEDURGRP			IEDURGRP1: <5		2	1
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		2	-1
TRTPN*IEDURGRP			IEDURGRP3: >=10		2	
TRTPN*IEDURGRP			IEDURGRP1: <5		3	
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		3	
TRTPN*IEDURGRP			IEDURGRP3: >=10		3	
TRTPN*IEDURGRP			IEDURGRP1: <5		900	-1
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		900	1
TRTPN*IEDURGRP			IEDURGRP3: >=10		900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	3	

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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	1	

FILE: stat2i.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	2	1
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	2	-1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	900	-1
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	900	1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	3	

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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.9
MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

FILE: stat2i.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
IEDURGRP			IEDURGRP1: <5			
IEDURGRP			IEDURGRP2: >=5 - <10			
IEDURGRP			IEDURGRP3: >=10			
AVISITN*IEDURGRP			IEDURGRP1: <5	3		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	3		
AVISITN*IEDURGRP			IEDURGRP3: >=10	3		
AVISITN*IEDURGRP			IEDURGRP1: <5	6		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	6		
AVISITN*IEDURGRP			IEDURGRP3: >=10	6		
AVISITN*IEDURGRP			IEDURGRP1: <5	10		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	10		
AVISITN*IEDURGRP			IEDURGRP3: >=10	10		
AVISITN*IEDURGRP			IEDURGRP1: <5	12		
AVISITN*IEDURGRP			IEDURGRP2: >=5 - <10	12		
AVISITN*IEDURGRP			IEDURGRP3: >=10	12		
TRTPN*IEDURGRP			IEDURGRP1: <5		1	
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		1	

FILE: stat2i.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*IEDURGRP			IEDURGRP3: >=10		1	
TRTPN*IEDURGRP			IEDURGRP1: <5		2	
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		2	
TRTPN*IEDURGRP			IEDURGRP3: >=10		2	
TRTPN*IEDURGRP			IEDURGRP1: <5		3	1
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		3	-1
TRTPN*IEDURGRP			IEDURGRP3: >=10		3	
TRTPN*IEDURGRP			IEDURGRP1: <5		900	-1
TRTPN*IEDURGRP			IEDURGRP2: >=5 - <10		900	1
TRTPN*IEDURGRP			IEDURGRP3: >=10		900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	3	

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STAT-3.9
 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	3	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	3	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	3	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	6	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	6	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	6	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	1	

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 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	3	1
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	3	-1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	10	900	-1
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	10	900	1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	10	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	1	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	2	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	3	

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The Mixed Procedure

Coefficients for Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	3	
AVISIT*TRTPN*IEDURGR			IEDURGRP1: <5	12	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP2: >=5 - <10	12	900	
AVISIT*TRTPN*IEDURGR			IEDURGRP3: >=10	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B	4.0987	4.8391	229	0.85	0.3979
Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B	-4.3930	4.8986	234	-0.90	0.3708
Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B	-5.6979	4.9432	238	-1.15	0.2502

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 MMRM Output for Test on Treatment by Years Since Index Traumatic Event Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B	9.7965	4.6722	230	2.10	0.0371
Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B	8.4917	4.6296	227	1.83	0.0679
Dummy W vs Dummy Z by GRP1 vs GRP3 at Phase B	-6.3581	4.5607	228	-1.39	0.1646
Dummy W vs Dummy Y by GRP1 vs GRP3 at Phase B	-7.6990	4.8791	232	-1.58	0.1159
Dummy W vs Dummy X by GRP1 vs GRP3 at Phase B	-5.6627	5.1608	237	-1.10	0.2736
Dummy X vs Dummy Z by GRP1 vs GRP3 at Phase B	-0.6954	5.2318	246	-0.13	0.8944
Dummy Y vs Dummy Z by GRP1 vs GRP3 at Phase B	1.3409	4.9193	237	0.27	0.7854
Dummy W vs Dummy Z by GRP2 vs GRP3 at Phase B	-10.4568	5.0012	225	-2.09	0.0377
Dummy W vs Dummy Y by GRP2 vs GRP3 at Phase B	-3.3060	5.5472	232	-0.60	0.5518
Dummy W vs Dummy X by GRP2 vs GRP3 at Phase B	0.03516	5.5043	234	0.01	0.9949
Dummy X vs Dummy Z by GRP2 vs GRP3 at Phase B	-10.4919	5.3725	238	-1.95	0.0520
Dummy Y vs Dummy Z by GRP2 vs GRP3 at Phase B	-7.1508	5.3525	230	-1.34	0.1829

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----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Contrasts

Label	Num DF	Den DF	F Value	Pr > F
TRT BY IEDURGRP AT Phase B	6	233	1.66	0.1326

Least Squares Means

Effect	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	3	1	-9.9445	1.7514	283	-5.68	<.0001	0.05	-13.3918	-6.4971
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	3	1	-5.4672	2.0143	275	-2.71	0.0071	0.05	-9.4326	-1.5018
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	3	1	-3.9250	1.8188	267	-2.16	0.0318	0.05	-7.5060	-0.3440
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	3	2	-5.7579	1.7681	280	-3.26	0.0013	0.05	-9.2383	-2.2774
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	3	2	-5.1226	1.9348	272	-2.65	0.0086	0.05	-8.9318	-1.3134
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	3	2	-1.9152	2.3174	276	-0.83	0.4093	0.05	-6.4771	2.6468
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	3	3	-5.3893	1.5461	276	-3.49	0.0006	0.05	-8.4329	-2.3456
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	3	3	-8.5774	1.9793	269	-4.33	<.0001	0.05	-12.4743	-4.6805
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	3	3	-6.2676	2.3712	275	-2.64	0.0087	0.05	-10.9357	-1.5995
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	3	900	-7.3896	1.6878	275	-4.38	<.0001	0.05	-10.7123	-4.0669
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	3	900	-5.3994	1.9831	276	-2.72	0.0069	0.05	-9.3033	-1.4955

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STAT-3.9
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----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	3	900	-6.1366	1.8423	269	-3.33	0.0010	0.05	-9.7638	-2.5094
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	6	1	-13.8396	2.1289	275	-6.50	<.0001	0.05	-18.0307	-9.6486
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	6	1	-12.7875	2.7147	286	-4.71	<.0001	0.05	-18.1307	-7.4442
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	6	1	-12.2938	2.2637	248	-5.43	<.0001	0.05	-16.7523	-7.8352
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	6	2	-7.1646	2.1749	274	-3.29	0.0011	0.05	-11.4462	-2.8830
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	6	2	-8.3548	2.3873	267	-3.50	0.0005	0.05	-13.0552	-3.6543
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	6	2	-10.0506	3.0427	274	-3.30	0.0011	0.05	-16.0406	-4.0605
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	6	3	-9.6547	1.9523	293	-4.95	<.0001	0.05	-13.4970	-5.8123
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	6	3	-9.5093	2.5318	259	-3.76	0.0002	0.05	-14.4948	-4.5237
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	6	3	-11.3311	2.9232	256	-3.88	0.0001	0.05	-17.0876	-5.5745
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	6	900	-9.8040	2.1099	275	-4.65	<.0001	0.05	-13.9576	-5.6503
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	6	900	-7.0710	2.3580	248	-3.00	0.0030	0.05	-11.7153	-2.4266
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	6	900	-10.0749	2.3071	258	-4.37	<.0001	0.05	-14.6181	-5.5318
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	10	1	-20.3259	2.2844	257	-8.90	<.0001	0.05	-24.8244	-15.8274
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	10	1	-15.6312	2.8358	238	-5.51	<.0001	0.05	-21.2176	-10.0447
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	10	1	-13.7442	2.3302	212	-5.90	<.0001	0.05	-18.3375	-9.1509
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	10	2	-12.2574	2.3812	269	-5.15	<.0001	0.05	-16.9455	-7.5692
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	10	2	-13.2605	2.5071	243	-5.29	<.0001	0.05	-18.1989	-8.3220
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	10	2	-11.3384	3.3073	248	-3.43	0.0007	0.05	-17.8525	-4.8243

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STAT-3.9
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 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	IEDURGRP	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	10	3	-11.4784	2.0289	252	-5.66	<.0001	0.05	-15.4741	-7.4827
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	10	3	-11.1766	2.6541	227	-4.21	<.0001	0.05	-16.4065	-5.9467
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	10	3	-12.5957	3.1208	237	-4.04	<.0001	0.05	-18.7437	-6.4476
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	10	900	-13.4531	2.2224	247	-6.05	<.0001	0.05	-17.8303	-9.0759
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	10	900	-4.6596	2.4634	224	-1.89	0.0598	0.05	-9.5140	0.1947
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	10	900	-13.2295	2.4429	236	-5.42	<.0001	0.05	-18.0421	-8.4169
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	12	1	-20.0500	2.4640	257	-8.14	<.0001	0.05	-24.9022	-15.1978
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	12	1	-18.5732	3.1983	255	-5.81	<.0001	0.05	-24.8717	-12.2747
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	12	1	-14.4185	2.5562	220	-5.64	<.0001	0.05	-19.4563	-9.3806
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	12	2	-13.0938	2.5687	262	-5.10	<.0001	0.05	-18.1518	-8.0359
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	12	2	-12.0585	2.7662	249	-4.36	<.0001	0.05	-17.5067	-6.6104
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	12	2	-12.0022	3.6062	249	-3.33	0.0010	0.05	-19.1047	-4.8996
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	12	3	-15.4052	2.1930	256	-7.02	<.0001	0.05	-19.7238	-11.0865
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	12	3	-12.2437	2.9138	235	-4.20	<.0001	0.05	-17.9842	-6.5031
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	12	3	-18.5335	3.3496	230	-5.53	<.0001	0.05	-25.1334	-11.9335
AVISIT*TRTPN*IEDURGR	IEDURGRP1: <5	12	900	-15.7377	2.4310	254	-6.47	<.0001	0.05	-20.5252	-10.9502
AVISIT*TRTPN*IEDURGR	IEDURGRP2: >=5 - <10	12	900	-5.1931	2.7322	238	-1.90	0.0586	0.05	-10.5755	0.1893
AVISIT*TRTPN*IEDURGR	IEDURGRP3: >=10	12	900	-13.6051	2.6073	230	-5.22	<.0001	0.05	-18.7425	-8.4677

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STAT-3.10
MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
AVISITN	4	3 6 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	[REDACTED]
COMBFL	2	N Y

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STAT-3.10
MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	299	[REDACTED]

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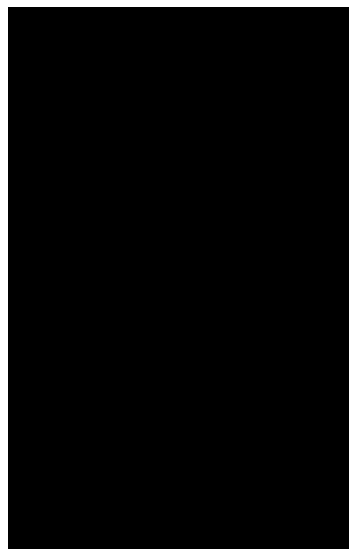
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STAT-3.10
MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
(Intent to Treat Sample)

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The Mixed Procedure



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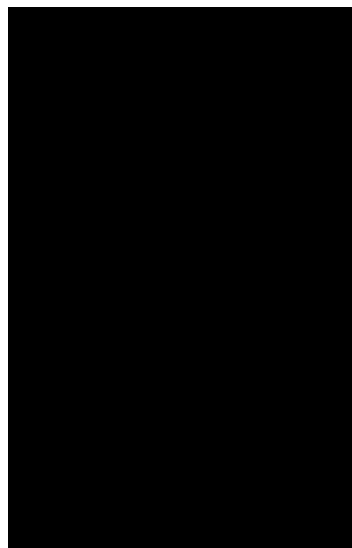
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STAT-3.10
MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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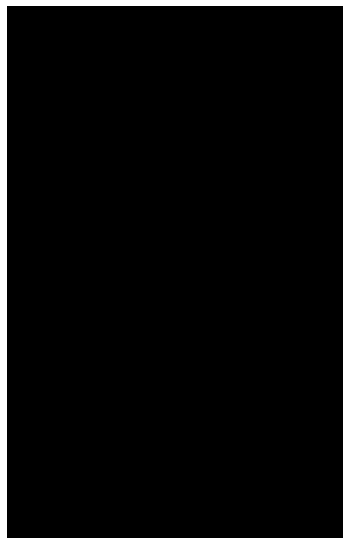
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STAT-3.10
MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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STAT-3.10
MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

AGEGRP2 3 [REDACTED]
AGEGRP 1: <30 AGEGRP 2: >=30 -
<40 AGEGRP 3: >=40

Dimensions

Covariance Parameters	10
Columns in X	116
Columns in Z	0
Subjects	299
Max Obs per Subject	4

Number of Observations

Number of Observations Read	996
Number of Observations Used	996
Number of Observations Not Used	0

FILE: stat2j.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.10
MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	7253.29512935	
1	2	6792.07841993	0.00034866
2	1	6791.10843333	0.00000952
3	1	6791.08379983	0.00000001

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	78.6821
UN(2,1)	SUBJID	53.1196
UN(2,2)	SUBJID	111.64
UN(3,1)	SUBJID	43.6449
UN(3,2)	SUBJID	89.4337
UN(3,3)	SUBJID	125.38
UN(4,1)	SUBJID	48.5602
UN(4,2)	SUBJID	88.0055

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STAT-3.10
MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,3)	SUBJID	104.89
UN(4,4)	SUBJID	146.59

Fit Statistics

-2 Res Log Likelihood	6791.1
AIC (Smaller is Better)	6811.1
AICC (Smaller is Better)	6811.3
BIC (Smaller is Better)	6848.1

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
9	462.21	<.0001

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STAT-3.10
MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
POOLCNTR	9	274	1.77	0.0748
COMBFL	1	274	4.09	0.0442
AVISITN	3	222	0.74	0.5315
TRTPN	3	261	3.57	0.0147
AVISITN*TRTPN	9	355	1.97	0.0417
AGEGRP2	2	267	0.21	0.8077
AVISITN*AGEGRP2	6	304	1.59	0.1492
TRTPN*AGEGRP2	6	264	1.28	0.2674
AVISITN*TRTPN*AGEGRP2	18	441	0.86	0.6339
BASE*AVISITN	4	234	15.42	<.0001

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STAT-3.10
MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
AGEGRP2			AGEGRP 1: <30			
AGEGRP2			AGEGRP 2: >=30 - <40			
AGEGRP2			AGEGRP 3: >=40			
AVISITN*AGEGRP2			AGEGRP 1: <30	3		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	3		
AVISITN*AGEGRP2			AGEGRP 3: >=40	3		
AVISITN*AGEGRP2			AGEGRP 1: <30	6		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	6		
AVISITN*AGEGRP2			AGEGRP 3: >=40	6		
AVISITN*AGEGRP2			AGEGRP 1: <30	10		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	10		
AVISITN*AGEGRP2			AGEGRP 3: >=40	10		
AVISITN*AGEGRP2			AGEGRP 1: <30	12		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	12		
AVISITN*AGEGRP2			AGEGRP 3: >=40	12		
TRTPN*AGEGRP2			AGEGRP 1: <30		1	1
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		1	-1

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*AGEGRP2			AGEGRP 3: >=40		1	
TRTPN*AGEGRP2			AGEGRP 1: <30		2	
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		2	
TRTPN*AGEGRP2			AGEGRP 3: >=40		2	
TRTPN*AGEGRP2			AGEGRP 1: <30		3	
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		3	
TRTPN*AGEGRP2			AGEGRP 3: >=40		3	
TRTPN*AGEGRP2			AGEGRP 1: <30		900	-1
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		900	1
TRTPN*AGEGRP2			AGEGRP 3: >=40		900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	3	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	1	1
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	1	-1

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	900	-1
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	900	1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	3	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

FILE: stat2j.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.10
MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

FILE: stat2j.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

FILE: stat2j.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
AGEGRP2			AGEGRP 1: <30			
AGEGRP2			AGEGRP 2: >=30 - <40			
AGEGRP2			AGEGRP 3: >=40			
AVISITN*AGEGRP2			AGEGRP 1: <30	3		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	3		
AVISITN*AGEGRP2			AGEGRP 3: >=40	3		
AVISITN*AGEGRP2			AGEGRP 1: <30	6		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	6		
AVISITN*AGEGRP2			AGEGRP 3: >=40	6		
AVISITN*AGEGRP2			AGEGRP 1: <30	10		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	10		
AVISITN*AGEGRP2			AGEGRP 3: >=40	10		
AVISITN*AGEGRP2			AGEGRP 1: <30	12		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	12		
AVISITN*AGEGRP2			AGEGRP 3: >=40	12		
TRTPN*AGEGRP2			AGEGRP 1: <30		1	1
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		1	-1

FILE: stat2j.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*AGEGRP2			AGEGRP 3: >=40		1	
TRTPN*AGEGRP2			AGEGRP 1: <30		2	
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		2	
TRTPN*AGEGRP2			AGEGRP 3: >=40		2	
TRTPN*AGEGRP2			AGEGRP 1: <30		3	-1
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		3	1
TRTPN*AGEGRP2			AGEGRP 3: >=40		3	
TRTPN*AGEGRP2			AGEGRP 1: <30		900	
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		900	
TRTPN*AGEGRP2			AGEGRP 3: >=40		900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	3	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	1	1
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	1	-1

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	3	-1
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	3	1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	3	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.10
MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
AGEGRP2			AGEGRP 1: <30			
AGEGRP2			AGEGRP 2: >=30 - <40			
AGEGRP2			AGEGRP 3: >=40			
AVISITN*AGEGRP2			AGEGRP 1: <30	3		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	3		
AVISITN*AGEGRP2			AGEGRP 3: >=40	3		
AVISITN*AGEGRP2			AGEGRP 1: <30	6		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	6		
AVISITN*AGEGRP2			AGEGRP 3: >=40	6		
AVISITN*AGEGRP2			AGEGRP 1: <30	10		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	10		
AVISITN*AGEGRP2			AGEGRP 3: >=40	10		
AVISITN*AGEGRP2			AGEGRP 1: <30	12		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	12		
AVISITN*AGEGRP2			AGEGRP 3: >=40	12		
TRTPN*AGEGRP2			AGEGRP 1: <30		1	1
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		1	-1

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*AGEGRP2			AGEGRP 3: >=40		1	
TRTPN*AGEGRP2			AGEGRP 1: <30		2	-1
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		2	1
TRTPN*AGEGRP2			AGEGRP 3: >=40		2	
TRTPN*AGEGRP2			AGEGRP 1: <30		3	
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		3	
TRTPN*AGEGRP2			AGEGRP 3: >=40		3	
TRTPN*AGEGRP2			AGEGRP 1: <30		900	
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		900	
TRTPN*AGEGRP2			AGEGRP 3: >=40		900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	3	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	1	1
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	1	-1

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	2	-1
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	2	1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	3	

FILE: stat2j.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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 PROTOCOL 331-201-00061

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.10
MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
POOLCNTR	[REDACTED]					
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
AGEGRP2			AGEGRP 1: <30			
AGEGRP2			AGEGRP 2: >=30 - <40			
AGEGRP2			AGEGRP 3: >=40			
AVISITN*AGEGRP2			AGEGRP 1: <30	3		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	3		
AVISITN*AGEGRP2			AGEGRP 3: >=40	3		
AVISITN*AGEGRP2			AGEGRP 1: <30	6		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	6		
AVISITN*AGEGRP2			AGEGRP 3: >=40	6		
AVISITN*AGEGRP2			AGEGRP 1: <30	10		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	10		
AVISITN*AGEGRP2			AGEGRP 3: >=40	10		
AVISITN*AGEGRP2			AGEGRP 1: <30	12		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	12		
AVISITN*AGEGRP2			AGEGRP 3: >=40	12		
TRTPN*AGEGRP2			AGEGRP 1: <30		1	
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		1	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*AGEGRP2			AGEGRP 3: >=40		1	
TRTPN*AGEGRP2			AGEGRP 1: <30		2	1
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		2	-1
TRTPN*AGEGRP2			AGEGRP 3: >=40		2	
TRTPN*AGEGRP2			AGEGRP 1: <30		3	
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		3	
TRTPN*AGEGRP2			AGEGRP 3: >=40		3	
TRTPN*AGEGRP2			AGEGRP 1: <30		900	-1
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		900	1
TRTPN*AGEGRP2			AGEGRP 3: >=40		900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	3	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	1	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	2	1
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	2	-1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	900	-1
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	900	1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	3	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

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STAT-3.10
MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
Intercept						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
POOLCNTR						
COMBFL		N				
COMBFL		Y				
AVISITN				3		
AVISITN				6		
AVISITN				10		
AVISITN				12		
TRTPN					1	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN					2	
TRTPN					3	
TRTPN					900	
AVISITN*TRTPN				3	1	
AVISITN*TRTPN				3	2	
AVISITN*TRTPN				3	3	
AVISITN*TRTPN				3	900	
AVISITN*TRTPN				6	1	
AVISITN*TRTPN				6	2	
AVISITN*TRTPN				6	3	
AVISITN*TRTPN				6	900	
AVISITN*TRTPN				10	1	
AVISITN*TRTPN				10	2	
AVISITN*TRTPN				10	3	
AVISITN*TRTPN				10	900	
AVISITN*TRTPN				12	1	
AVISITN*TRTPN				12	2	
AVISITN*TRTPN				12	3	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISITN*TRTPN				12	900	
AGEGRP2			AGEGRP 1: <30			
AGEGRP2			AGEGRP 2: >=30 - <40			
AGEGRP2			AGEGRP 3: >=40			
AVISITN*AGEGRP2			AGEGRP 1: <30	3		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	3		
AVISITN*AGEGRP2			AGEGRP 3: >=40	3		
AVISITN*AGEGRP2			AGEGRP 1: <30	6		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	6		
AVISITN*AGEGRP2			AGEGRP 3: >=40	6		
AVISITN*AGEGRP2			AGEGRP 1: <30	10		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	10		
AVISITN*AGEGRP2			AGEGRP 3: >=40	10		
AVISITN*AGEGRP2			AGEGRP 1: <30	12		
AVISITN*AGEGRP2			AGEGRP 2: >=30 - <40	12		
AVISITN*AGEGRP2			AGEGRP 3: >=40	12		
TRTPN*AGEGRP2			AGEGRP 1: <30		1	
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		1	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
TRTPN*AGEGRP2			AGEGRP 3: >=40		1	
TRTPN*AGEGRP2			AGEGRP 1: <30		2	
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		2	
TRTPN*AGEGRP2			AGEGRP 3: >=40		2	
TRTPN*AGEGRP2			AGEGRP 1: <30		3	1
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		3	-1
TRTPN*AGEGRP2			AGEGRP 3: >=40		3	
TRTPN*AGEGRP2			AGEGRP 1: <30		900	-1
TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40		900	1
TRTPN*AGEGRP2			AGEGRP 3: >=40		900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	3	

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	3	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	3	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	3	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	6	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	6	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	6	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	1	

FILE: stat2j.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAF/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-3.10 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Coefficients for Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	3	1
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	3	-1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	10	900	-1
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	10	900	1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	10	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	1	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	2	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	3	

FILE: stat2j.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.10
MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
(Intent to Treat Sample)

Parameter Code=CAPSTOT

The Mixed Procedure

Coefficients for Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Row1
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	3	
AVISIT*TRTPN*AGEGRP2			AGEGRP 1: <30	12	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 2: >=30 - <40	12	900	
AVISIT*TRTPN*AGEGRP2			AGEGRP 3: >=40	12	900	
BASE*AVISITN				3		
BASE*AVISITN				6		
BASE*AVISITN				10		
BASE*AVISITN				12		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy W vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]	-8.0993	5.5169	233	-1.47	0.1434
Dummy W vs Dummy Y by GRP1 vs GRP2 at Phase B [REDACTED]	-7.5352	5.6239	238	-1.34	0.1816
Dummy W vs Dummy X by GRP1 vs GRP2 at Phase B [REDACTED]	-6.7764	5.7919	248	-1.17	0.2431

FILE: stat2j.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t
Dummy X vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]	-1.3229	5.9550	242	-0.22	0.8244
Dummy Y vs Dummy Z by GRP1 vs GRP2 at Phase B [REDACTED]	-0.5641	5.8225	236	-0.10	0.9229
Dummy W vs Dummy Z by GRP1 vs GRP3 at Phase B [REDACTED]	-9.7301	5.3417	228	-1.82	0.0698
Dummy W vs Dummy Y by GRP1 vs GRP3 at Phase B [REDACTED]	-9.9839	5.2575	234	-1.90	0.0588
Dummy W vs Dummy X by GRP1 vs GRP3 at Phase B [REDACTED]	-3.3795	5.5924	245	-0.60	0.5462
Dummy X vs Dummy Z by GRP1 vs GRP3 at Phase B [REDACTED]	-6.3506	5.5451	240	-1.15	0.2532
Dummy Y vs Dummy Z by GRP1 vs GRP3 at Phase B [REDACTED]	0.2538	5.2474	235	0.05	0.9615
Dummy W vs Dummy Z by GRP2 vs GRP3 at Phase B [REDACTED]	-1.6308	4.4276	234	-0.37	0.7130
Dummy W vs Dummy Y by GRP2 vs GRP3 at Phase B [REDACTED]	-2.4487	4.6629	230	-0.53	0.6000
Dummy W vs Dummy X by GRP2 vs GRP3 at Phase B [REDACTED]	3.3969	4.6771	237	0.73	0.4684
Dummy X vs Dummy Z by GRP2 vs GRP3 at Phase B [REDACTED]	-5.0277	4.6396	240	-1.08	0.2796
Dummy Y vs Dummy Z by GRP2 vs GRP3 at Phase B [REDACTED]	0.8179	4.6172	232	0.18	0.8595

FILE: stat2j.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Contrasts

Label	Num DF	Den DF	F Value	Pr > F
TRT BY AGEGRP2 AT Phase B [REDACTED]	6	238	1.08	0.3753

Least Squares Means

Effect	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	3	1	-9.6327	2.2552	274	-4.27	<.0001	0.05	-14.0725	-5.1929
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	3	1	-4.8803	1.6447	276	-2.97	0.0033	0.05	-8.1180	-1.6427
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	3	1	-6.3674	1.7746	282	-3.59	0.0004	0.05	-9.8606	-2.8742
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	3	2	-4.0192	2.4594	273	-1.63	0.1034	0.05	-8.8610	0.8226
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	3	2	-4.8855	1.9219	273	-2.54	0.0116	0.05	-8.6692	-1.1019
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	3	2	-4.6841	1.7029	285	-2.75	0.0063	0.05	-8.0360	-1.3323
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	3	3	-5.9120	2.1981	281	-2.69	0.0076	0.05	-10.2388	-1.5852
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	3	3	-4.0711	2.1422	271	-1.90	0.0584	0.05	-8.2885	0.1463
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	3	3	-7.4602	1.5101	274	-4.94	<.0001	0.05	-10.4330	-4.4874
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	3	900	-4.6844	2.5915	280	-1.81	0.0717	0.05	-9.7856	0.4169
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	3	900	-5.6220	1.7513	272	-3.21	0.0015	0.05	-9.0699	-2.1741

FILE: stat2j.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
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BREXPIPIRAZOLE
 PROTOCOL 331-201-00061

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction [REDACTED]
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	3	900	-7.2208	1.5521	277	-4.65	<.0001	0.05	-10.2763	-4.1654
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	6	1	-16.3627	2.9100	281	-5.62	<.0001	0.05	-22.0909	-10.6345
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	6	1	-12.8370	1.9778	251	-6.49	<.0001	0.05	-16.7323	-8.9418
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	6	1	-10.2105	2.1547	271	-4.74	<.0001	0.05	-14.4526	-5.9684
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	6	2	-2.9996	3.0323	268	-0.99	0.3234	0.05	-8.9696	2.9705
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	6	2	-10.8046	2.4704	282	-4.37	<.0001	0.05	-15.6673	-5.9419
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	6	2	-8.3290	1.9954	265	-4.17	<.0001	0.05	-12.2579	-4.4001
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	6	3	-6.4684	2.8121	284	-2.30	0.0222	0.05	-12.0035	-0.9332
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	6	3	-8.7999	2.5819	248	-3.41	0.0008	0.05	-13.8851	-3.7147
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	6	3	-11.5405	1.8683	279	-6.18	<.0001	0.05	-15.2182	-7.8628
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	6	900	-7.3593	2.9847	244	-2.47	0.0144	0.05	-13.2383	-1.4802
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	6	900	-10.8294	2.1850	258	-4.96	<.0001	0.05	-15.1320	-6.5268
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	6	900	-8.2133	1.8542	272	-4.43	<.0001	0.05	-11.8636	-4.5630
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	10	1	-20.9788	3.0702	233	-6.83	<.0001	0.05	-27.0278	-14.9299
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	10	1	-15.8923	2.1973	236	-7.23	<.0001	0.05	-20.2210	-11.5635
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	10	1	-14.3246	2.3143	236	-6.19	<.0001	0.05	-18.8839	-9.7654
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	10	2	-13.5275	3.5320	276	-3.83	0.0002	0.05	-20.4805	-6.5745
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	10	2	-15.2174	2.7361	255	-5.56	<.0001	0.05	-20.6056	-9.8291
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	10	2	-10.2528	2.1766	245	-4.71	<.0001	0.05	-14.5400	-5.9656

FILE: stat2j.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAF/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat2.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIPIRAZOLE STAT-3.10 FINAL

BREXPIPIRAZOLE
 PROTOCOL 331-201-00061

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STAT-3.10
 MMRM Output for Test on Treatment by Age (<30 vs 30-40 vs >=40) Interaction
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----											
The Mixed Procedure											
Least Squares Means											
Effect	AGEGRP2	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	10	3	-9.0130	3.1252	255	-2.88	0.0043	0.05	-15.1675	-2.8584
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	10	3	-11.4616	2.8529	235	-4.02	<.0001	0.05	-17.0822	-5.8410
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	10	3	-12.3427	1.9725	235	-6.26	<.0001	0.05	-16.2289	-8.4565
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	10	900	-7.9754	3.2587	229	-2.45	0.0151	0.05	-14.3963	-1.5545
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	10	900	-10.9881	2.4402	241	-4.50	<.0001	0.05	-15.7949	-6.1813
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	10	900	-11.0513	1.9753	244	-5.59	<.0001	0.05	-14.9421	-7.1604
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	12	1	-20.7564	3.3785	245	-6.14	<.0001	0.05	-27.4109	-14.1018
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	12	1	-18.2342	2.3978	238	-7.60	<.0001	0.05	-22.9579	-13.5105
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	12	1	-14.2673	2.5224	246	-5.66	<.0001	0.05	-19.2355	-9.2991
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	12	2	-13.7542	3.8897	274	-3.54	0.0005	0.05	-21.4116	-6.0968
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	12	2	-14.2271	2.9780	255	-4.78	<.0001	0.05	-20.0917	-8.3626
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	12	2	-10.9756	2.3568	245	-4.66	<.0001	0.05	-15.6178	-6.3333
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	12	3	-10.8895	3.4445	266	-3.16	0.0018	0.05	-17.6714	-4.1076
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	12	3	-14.3849	3.0599	229	-4.70	<.0001	0.05	-20.4141	-8.3558
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	12	3	-16.7603	2.1294	239	-7.87	<.0001	0.05	-20.9552	-12.5654
AVISIT*TRTPN*AGEGRP2	AGEGRP 1: <30	12	900	-8.4619	3.6991	254	-2.29	0.0230	0.05	-15.7469	-1.1770
AVISIT*TRTPN*AGEGRP2	AGEGRP 2: >=30 - <40	12	900	-14.0999	2.6556	243	-5.31	<.0001	0.05	-19.3308	-8.8690
AVISIT*TRTPN*AGEGRP2	AGEGRP 3: >=40	12	900	-11.2824	2.1187	245	-5.33	<.0001	0.05	-15.4556	-7.1093

FILE: stat2j.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIPIRAZOLE STAT-3.10 FINAL

BREXPIRAZOLE
PROTOCOL 331-201-00061

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STAT-4.1.1
Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=KENWARDROGER
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
AVISITN	4	3 6 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	[REDACTED]
COMBFL	2	N Y

SOURCE: MMRMOUT; TABLE: statlaa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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PROTOCOL 331-201-00061

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STAT-4.1.1
Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=KENWARDROGER
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	299	[REDACTED]

SOURCE: MMRMOUT; TABLE: statlaa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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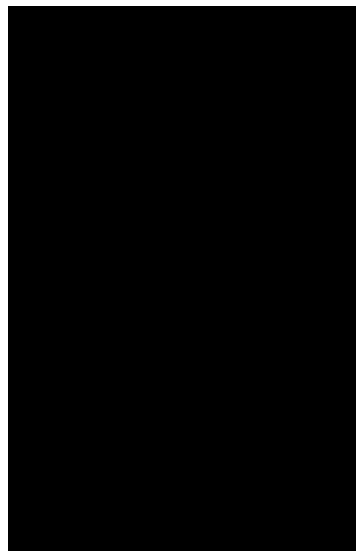
BREXPIRAZOLE
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STAT-4.1.1
Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=KENWARDROGER
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



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PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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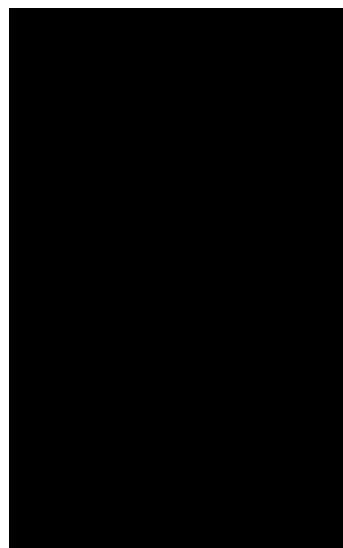
BREXPIPIRAZOLE
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STAT-4.1.1
Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=KENWARDROGER
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



SOURCE: MMRMOUT; TABLE: statlaa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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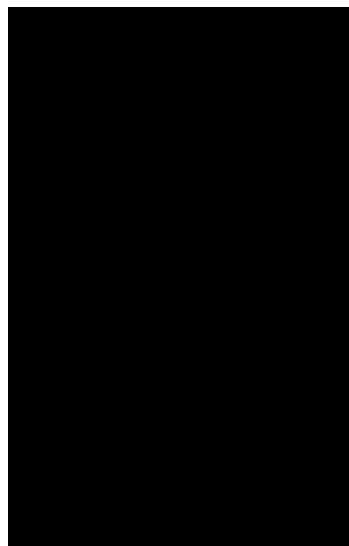
BREXPIRAZOLE
PROTOCOL 331-201-00061

5 OF 14

STAT-4.1.1
Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=KENWARDROGER
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



SOURCE: MMRMOUT; TABLE: statlaa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.1.1 FINAL

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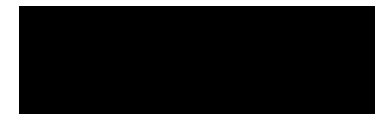
BREXPIRAZOLE
PROTOCOL 331-201-00061

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STAT-4.1.1
Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=KENWARDROGER
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



Dimensions

Covariance Parameters	10
Columns in X	41
Columns in Z	0
Subjects	299
Max Obs per Subject	4

Number of Observations

Number of Observations Read	996
Number of Observations Used	996
Number of Observations Not Used	0

SOURCE: MMRMOUT; TABLE: statlaa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4 1.1
Proc Mixed Output for Change ██████████ in CAPS-5 Total Score, MMRM (UN), DDFM=KENWARDROGER
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	7419.63261777	
1	2	6942.08156810	0.00073594
2	1	6939.93600307	0.00003899
3	1	6939.83150668	0.00000014
4	1	6939.83114836	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	78.1269
UN(2,1)	SUBJID	52.5499
UN(2,2)	SUBJID	113.08
UN(3,1)	SUBJID	43.8955
UN(3,2)	SUBJID	89.6163
UN(3,3)	SUBJID	124.63
UN(4,1)	SUBJID	48.3003

SOURCE: MMRMOUT; TABLE: statlaa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.1.1
Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=KENWARDROGER
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,2)	SUBJID	89.7025
UN(4,3)	SUBJID	105.06
UN(4,4)	SUBJID	146.78

Fit Statistics

-2 Res Log Likelihood	6939.8
AIC (Smaller is Better)	6959.8
AICC (Smaller is Better)	6960.1
BIC (Smaller is Better)	6996.8

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
9	479.80	<.0001

SOURCE: MMRMOUT; TABLE: statlaa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.1.1
 Proc Mixed Output for Change ██████████ in CAPS-5 Total Score, MMRM (UN), DDFM=KENWARDROGER
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Solution for Fixed Effects

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t
Intercept					3.8537	3.4109	345	1.13	0.2593
AVISITN			3		0.6901	2.5973	250	0.27	0.7907
AVISITN			6		-0.2730	2.1267	217	-0.13	0.8980
AVISITN			10		1.0916	1.8901	214	0.58	0.5642
AVISITN			12		0				
TRTPN				1	-5.6267	2.1147	241	-2.66	0.0083
TRTPN				2	-0.5710	2.1994	247	-0.26	0.7954
TRTPN				3	-3.2353	2.1222	240	-1.52	0.1287
TRTPN				900	0				
AVISITN*TRTPN			3	1	5.3923	2.0073	252	2.69	0.0077
AVISITN*TRTPN			3	2	2.2048	2.0904	259	1.05	0.2925
AVISITN*TRTPN			3	3	3.2522	2.0062	247	1.62	0.1063
AVISITN*TRTPN			3	900	0				
AVISITN*TRTPN			6	1	1.8609	1.6533	223	1.13	0.2616
AVISITN*TRTPN			6	2	1.4711	1.7360	225	0.85	0.3977
AVISITN*TRTPN			6	3	2.4279	1.6511	219	1.47	0.1429
AVISITN*TRTPN			6	900	0				
AVISITN*TRTPN			10	1	-0.3608	1.4658	216	-0.25	0.8058

SOURCE: MMRMOUT; TABLE: statlaa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.1.1
 Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=KENWARDROGER
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Solution for Fixed Effects

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t
AVISITN*TRTPN			10	2	-1.1719	1.5456	217	-0.76	0.4491
AVISITN*TRTPN			10	3	2.3246	1.4625	214	1.59	0.1134
AVISITN*TRTPN			10	900	0				
AVISITN*TRTPN			12	1	0				
AVISITN*TRTPN			12	2	0				
AVISITN*TRTPN			12	3	0				
AVISITN*TRTPN			12	900	0				
POOLCNTR					0.9907	3.0086	279	0.33	0.7422
POOLCNTR					-0.7991	2.9472	281	-0.27	0.7865
POOLCNTR					0.1817	2.4770	281	0.07	0.9416
POOLCNTR					0.3656	2.2129	285	0.17	0.8689
POOLCNTR					-1.7756	2.3317	282	-0.76	0.4470
POOLCNTR					-3.9197	2.3813	285	-1.65	0.1009
POOLCNTR					-2.3470	2.3914	285	-0.98	0.3272
POOLCNTR					-4.6066	2.4078	280	-1.91	0.0567
POOLCNTR					-3.8650	2.4765	284	-1.56	0.1197
POOLCNTR					0				
COMBFL		N			2.4761	1.2332	282	2.01	0.0456

SOURCE: MMRMOUT; TABLE: statlaa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.1.1
 Proc Mixed Output for Change ██████████ in CAPS-5 Total Score, MMRM (UN), DDFM=KENWARDROGER
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Solution for Fixed Effects

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t
COMBFL		Y			0				
BASE*AVISITN			3		-0.2945	0.04717	285	-6.24	<.0001
BASE*AVISITN			6		-0.3423	0.05752	269	-5.95	<.0001
BASE*AVISITN			10		-0.4252	0.06194	247	-6.86	<.0001
BASE*AVISITN			12		-0.4287	0.06757	250	-6.34	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
AVISITN	3	230	0.80	0.4940
TRTPN	3	268	2.87	0.0370
AVISITN*TRTPN	9	365	1.91	0.0487
POOLCNTR	9	281	1.68	0.0934
COMBFL	1	282	4.03	0.0456
BASE*AVISITN	4	243	15.03	<.0001

SOURCE: MMRMOUT; TABLE: statlaa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.1.1
 Proc Mixed Output for Change ██████████ in CAPS-5 Total Score, MMRM (UN), DDFM=KENWARDROGER
 (Intent to Treat Sample)

 Parameter Code=CAPSTOT -----

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
WEEK3 1 vs 900	-0.2343	1.4361	280	-0.16	0.8705	0.05	-3.0612	2.5925
WEEK6 1 vs 900	-3.7658	1.7875	262	-2.11	0.0361	0.05	-7.2855	-0.2460
WEEK10 1 vs 900	-5.9875	1.9283	237	-3.10	0.0021	0.05	-9.7864	-2.1885
WEEK12 1 vs 900	-5.6267	2.1147	241	-2.66	0.0083	0.05	-9.7922	-1.4611
WEEK3 1 vs 2	-1.8682	1.4949	282	-1.25	0.2125	0.05	-4.8107	1.0744
WEEK6 1 vs 2	-4.6659	1.8691	267	-2.50	0.0131	0.05	-8.3458	-0.9859
WEEK10 1 vs 2	-4.2446	2.0394	247	-2.08	0.0384	0.05	-8.2614	-0.2277
WEEK12 1 vs 2	-5.0557	2.2352	249	-2.26	0.0246	0.05	-9.4580	-0.6534
WEEK3 1 vs 3	-0.2512	1.4560	281	-0.17	0.8631	0.05	-3.1172	2.6148
WEEK6 1 vs 3	-2.9583	1.8330	266	-1.61	0.1077	0.05	-6.5672	0.6507
WEEK10 1 vs 3	-5.0767	1.9703	237	-2.58	0.0106	0.05	-8.9582	-1.1952
WEEK12 1 vs 3	-2.3913	2.1550	241	-1.11	0.2682	0.05	-6.6364	1.8537
WEEK3 2 vs 900	1.6338	1.4809	280	1.10	0.2709	0.05	-1.2814	4.5490
WEEK6 2 vs 900	0.9001	1.8390	263	0.49	0.6249	0.05	-2.7208	4.5211
WEEK10 2 vs 900	-1.7429	2.0102	246	-0.87	0.3868	0.05	-5.7022	2.2164
WEEK12 2 vs 900	-0.5710	2.1994	247	-0.26	0.7954	0.05	-4.9030	3.7611
WEEK3 3 vs 900	0.01689	1.4412	279	0.01	0.9907	0.05	-2.8202	2.8540
WEEK6 3 vs 900	-0.8075	1.8057	262	-0.45	0.6551	0.05	-4.3630	2.7481
WEEK10 3 vs 900	-0.9108	1.9445	237	-0.47	0.6399	0.05	-4.7416	2.9200
WEEK12 3 vs 900	-3.2353	2.1222	240	-1.52	0.1287	0.05	-7.4158	0.9451

SOURCE: MMRMOUT; TABLE: statlaa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT=4.1.1
 Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=KENWARDROGER
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Least Squares Means

Effect	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN	3	1	-6.4581	1.0908	290	-5.92	<.0001	0.05	-8.6049	-4.3112
AVISITN*TRTPN	3	2	-4.5899	1.1749	291	-3.91	0.0001	0.05	-6.9023	-2.2775
AVISITN*TRTPN	3	3	-6.2068	1.1067	286	-5.61	<.0001	0.05	-8.3850	-4.0286
AVISITN*TRTPN	3	900	-6.2237	1.0787	286	-5.77	<.0001	0.05	-8.3469	-4.1006
AVISITN*TRTPN	6	1	-12.6460	1.3343	281	-9.48	<.0001	0.05	-15.2725	-10.0195
AVISITN*TRTPN	6	2	-7.9801	1.4338	300	-5.57	<.0001	0.05	-10.8018	-5.1585
AVISITN*TRTPN	6	3	-9.6877	1.3688	291	-7.08	<.0001	0.05	-12.3817	-6.9938
AVISITN*TRTPN	6	900	-8.8803	1.3025	276	-6.82	<.0001	0.05	-11.4444	-6.3161
AVISITN*TRTPN	10	1	-16.4384	1.4287	251	-11.51	<.0001	0.05	-19.2522	-13.6247
AVISITN*TRTPN	10	2	-12.1939	1.5685	285	-7.77	<.0001	0.05	-15.2812	-9.1065
AVISITN*TRTPN	10	3	-11.3617	1.4604	258	-7.78	<.0001	0.05	-14.2374	-8.4860
AVISITN*TRTPN	10	900	-10.4510	1.3976	254	-7.48	<.0001	0.05	-13.2033	-7.6986
AVISITN*TRTPN	12	1	-17.2944	1.5619	259	-11.07	<.0001	0.05	-20.3700	-14.2188
AVISITN*TRTPN	12	2	-12.2387	1.7024	283	-7.19	<.0001	0.05	-15.5897	-8.8878
AVISITN*TRTPN	12	3	-14.9031	1.5808	260	-9.43	<.0001	0.05	-18.0160	-11.7902
AVISITN*TRTPN	12	900	-11.6677	1.5210	260	-7.67	<.0001	0.05	-14.6627	-8.6728

SOURCE: MMRMOUT; TABLE: statlaa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.1.1
Proc Mixed Output for Change ██████████ in CAPS-5 Total Score, MMRM (UN), DDFM=KENWARDROGER
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Tests of Effect Slices

Effect	Analysis Visit (N)	Num DF	Den DF	F Value	Pr > F
AVISITN*TRTPN	3	3	280	0.65	0.5864
AVISITN*TRTPN	6	3	264	2.42	0.0667
AVISITN*TRTPN	10	3	241	3.70	0.0123
AVISITN*TRTPN	12	3	244	2.90	0.0356

SOURCE: MMRMOUT; TABLE: statlaa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.1.2
Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=SATTERTHWAITE
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
AVISITN	4	3 6 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	[REDACTED]
COMBFL	2	N Y

SOURCE: MMRMOUT; TABLE: statlab.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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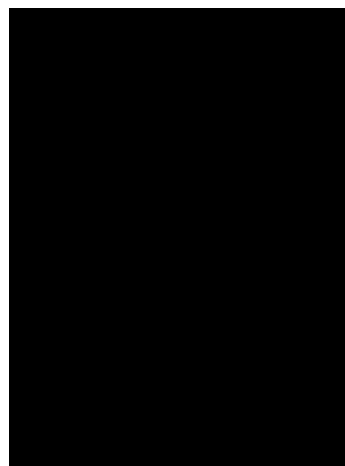
STAT-4.1.2
Proc Mixed Output for Change ██████████ in CAPS-5 Total Score, MMRM (UN), DDFM=SATTERTHWAITE
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	299	



SOURCE: MMRMOUT; TABLE: statlab.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.1.2 FINAL

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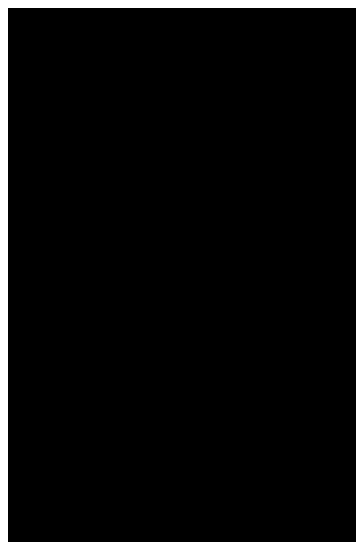
BREXPIRAZOLE
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STAT-4.1.2
Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=SATTERTHWAITE
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



SOURCE: MMRMOUT; TABLE: statlab.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.1.2 FINAL

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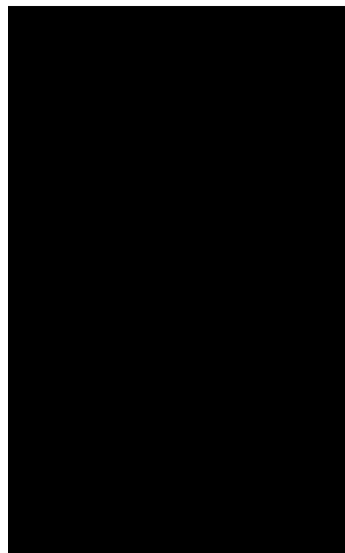
BREXPIRAZOLE
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STAT-4.1.2
Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=SATTERTHWAITE
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



SOURCE: MMRMOUT; TABLE: statlab.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.1.2 FINAL

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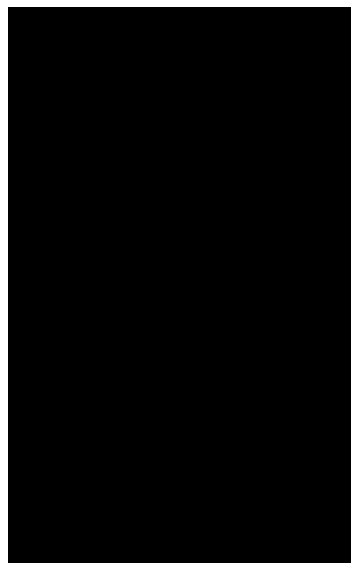
BREXPIRAZOLE
PROTOCOL 331-201-00061

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STAT-4.1.2
Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=SATTERTHWAITE
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



SOURCE: MMRMOUT; TABLE: statlab.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.1.2 FINAL

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STAT-4.1.2
Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=SATTERTHWAITE
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure



Dimensions

Covariance Parameters	10
Columns in X	41
Columns in Z	0
Subjects	299
Max Obs per Subject	4

Number of Observations

Number of Observations Read	996
Number of Observations Used	996
Number of Observations Not Used	0

SOURCE: MMRMOUT; TABLE: statlab.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.1.2 FINAL

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STAT-4 1.2
Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=SATTERTHWAITE
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	7419.63261777	
1	2	6942.08156810	0.00073594
2	1	6939.93600307	0.00003899
3	1	6939.83150668	0.00000014
4	1	6939.83114836	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	78.1269
UN(2,1)	SUBJID	52.5499
UN(2,2)	SUBJID	113.08
UN(3,1)	SUBJID	43.8955
UN(3,2)	SUBJID	89.6163
UN(3,3)	SUBJID	124.63
UN(4,1)	SUBJID	48.3003

SOURCE: MMRMOUT; TABLE: statlab.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.1.2 FINAL

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STAT-4.1.2
Proc Mixed Output for Change ██████████ in CAPS-5 Total Score, MMRM (UN), DDFM=SATTERTHWAITE
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,2)	SUBJID	89.7025
UN(4,3)	SUBJID	105.06
UN(4,4)	SUBJID	146.78

Fit Statistics

-2 Res Log Likelihood	6939.8
AIC (Smaller is Better)	6959.8
AICC (Smaller is Better)	6960.1
BIC (Smaller is Better)	6996.8

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
9	479.80	<.0001

SOURCE: MMRMOUT; TABLE: statlab.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.1.2 FINAL

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STAT-4.1.2
 Proc Mixed Output for Change [REDACTED] in CAPS-5 Total Score, MMRM (UN), DDFM=SATTERTHWAITE
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
AVISITN	3	234	0.81	0.4893
TRTPN	3	268	2.87	0.0369
AVISITN*TRTPN	9	240	1.94	0.0469
POOLCNTR	9	281	1.72	0.0840
COMBFL	1	282	4.12	0.0433
BASE*AVISITN	4	250	15.26	<.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
WEEK3 1 vs 900	-0.2343	1.4358	280	-0.16	0.8705	0.05	-3.0606	2.5919
WEEK6 1 vs 900	-3.7658	1.7865	262	-2.11	0.0360	0.05	-7.2836	-0.2479
WEEK10 1 vs 900	-5.9875	1.9265	237	-3.11	0.0021	0.05	-9.7827	-2.1922
WEEK12 1 vs 900	-5.6267	2.1121	241	-2.66	0.0082	0.05	-9.7872	-1.4661
WEEK3 1 vs 2	-1.8682	1.4943	282	-1.25	0.2123	0.05	-4.8096	1.0733
WEEK6 1 vs 2	-4.6659	1.8678	267	-2.50	0.0131	0.05	-8.3432	-0.9885
WEEK10 1 vs 2	-4.2446	2.0368	247	-2.08	0.0382	0.05	-8.2562	-0.2329

SOURCE: MMRMOUT; TABLE: statlab.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.1.2 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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STAT-4.1.2
 Proc Mixed Output for Change ██████████ in CAPS-5 Total Score, MMRM (UN), DDFM=SATTERTHWAITE
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
WEEK12 1 vs 2	-5.0557	2.2318	249	-2.27	0.0244	0.05	-9.4513	-0.6600
WEEK3 1 vs 3	-0.2512	1.4556	281	-0.17	0.8631	0.05	-3.1164	2.6140
WEEK6 1 vs 3	-2.9583	1.8317	266	-1.62	0.1075	0.05	-6.5647	0.6481
WEEK10 1 vs 3	-5.0767	1.9683	237	-2.58	0.0105	0.05	-8.9542	-1.1991
WEEK12 1 vs 3	-2.3913	2.1524	241	-1.11	0.2677	0.05	-6.6314	1.8487
WEEK3 2 vs 900	1.6338	1.4805	280	1.10	0.2707	0.05	-1.2805	4.5481
WEEK6 2 vs 900	0.9001	1.8379	263	0.49	0.6247	0.05	-2.7188	4.5191
WEEK10 2 vs 900	-1.7429	2.0076	246	-0.87	0.3862	0.05	-5.6973	2.2114
WEEK12 2 vs 900	-0.5710	2.1963	247	-0.26	0.7951	0.05	-4.8968	3.7548
WEEK3 3 vs 900	0.01689	1.4411	279	0.01	0.9907	0.05	-2.8199	2.8536
WEEK6 3 vs 900	-0.8075	1.8048	262	-0.45	0.6549	0.05	-4.3611	2.7462
WEEK10 3 vs 900	-0.9108	1.9427	237	-0.47	0.6396	0.05	-4.7378	2.9163
WEEK12 3 vs 900	-3.2353	2.1199	240	-1.53	0.1283	0.05	-7.4112	0.9406

SOURCE: MMRMOUT; TABLE: statlab.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.1.2
 Proc Mixed Output for Change ██████████ in CAPS-5 Total Score, MMRM (UN), DDFM=SATTERTHWAITE
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Least Squares Means

Effect	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN	3	1	-6.4581	1.0890	290	-5.93	<.0001	0.05	-8.6014	-4.3147
AVISITN*TRTPN	3	2	-4.5899	1.1726	291	-3.91	0.0001	0.05	-6.8978	-2.2821
AVISITN*TRTPN	3	3	-6.2068	1.1049	286	-5.62	<.0001	0.05	-8.3816	-4.0321
AVISITN*TRTPN	3	900	-6.2237	1.0770	286	-5.78	<.0001	0.05	-8.3436	-4.1038
AVISITN*TRTPN	6	1	-12.6460	1.3324	281	-9.49	<.0001	0.05	-15.2687	-10.0233
AVISITN*TRTPN	6	2	-7.9801	1.4312	300	-5.58	<.0001	0.05	-10.7966	-5.1637
AVISITN*TRTPN	6	3	-9.6877	1.3666	291	-7.09	<.0001	0.05	-12.3774	-6.9981
AVISITN*TRTPN	6	900	-8.8803	1.3008	276	-6.83	<.0001	0.05	-11.4410	-6.3195
AVISITN*TRTPN	10	1	-16.4384	1.4264	251	-11.52	<.0001	0.05	-19.2476	-13.6293
AVISITN*TRTPN	10	2	-12.1939	1.5647	285	-7.79	<.0001	0.05	-15.2737	-9.1140
AVISITN*TRTPN	10	3	-11.3617	1.4578	258	-7.79	<.0001	0.05	-14.2324	-8.4910
AVISITN*TRTPN	10	900	-10.4510	1.3952	254	-7.49	<.0001	0.05	-13.1986	-7.7033
AVISITN*TRTPN	12	1	-17.2944	1.5590	259	-11.09	<.0001	0.05	-20.3644	-14.2244
AVISITN*TRTPN	12	2	-12.2387	1.6982	283	-7.21	<.0001	0.05	-15.5815	-8.8959
AVISITN*TRTPN	12	3	-14.9031	1.5781	260	-9.44	<.0001	0.05	-18.0107	-11.7955
AVISITN*TRTPN	12	900	-11.6677	1.5183	260	-7.68	<.0001	0.05	-14.6574	-8.6781

SOURCE: MMRMOUT; TABLE: statlab.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.1.2
Proc Mixed Output for Change ██████████ in CAPS-5 Total Score, MMRM (UN), DDFM=SATTERTHWAITE
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Tests of Effect Slices

Effect	Analysis	Num DF	Den DF	F Value	Pr > F
	Visit (N)				
AVISITN*TRTPN	3	3	280	0.65	0.5861
AVISITN*TRTPN	6	3	264	2.42	0.0664
AVISITN*TRTPN	10	3	241	3.71	0.0122
AVISITN*TRTPN	12	3	244	2.91	0.0353

SOURCE: MMRMOUT; TABLE: statlab.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIRAZOLE
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1 OF 6

STAT-4.2
Proc GLM Output for Change [REDACTED] in CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT Analysis Visit (N)=10 -----

The GLM Procedure

Class Level Information

Class	Levels	Values
TRTPN	4	1 2 3 900
POOLCNTR	10	[REDACTED]
COMBFL	2	N Y

Number of Observations Read 307
Number of Observations Used 307

SOURCE: GLMOUT; TABLE: stat1b.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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2 OF 6

STAT-4.2
Proc GLM Output for Change [REDACTED] in CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT Analysis Visit (N)=10 -----

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	14	9591.13489	685.08106	5.67	<.0001
Error	292	35268.22668	120.78160		
Corrected Total	306	44859.36156			

R-Square	Coeff Var	Root MSE	CHG Mean
0.213805	-100.3256	10.99007	-10.95440

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRTPN	3	1146.283220	382.094407	3.16	0.0249
POOLCNTR	9	2023.768218	224.863135	1.86	0.0574
COMBFL	1	4.280406	4.280406	0.04	0.8508
BASE	1	5480.115400	5480.115400	45.37	<.0001

SOURCE: GLMOUT; TABLE: stat1b.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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----- Parameter Code=CAPSTOT Analysis Visit (N)=10 -----

		The GLM Procedure			
Level of TRTPN	N	-----CHG-----		-----BASE-----	
		Mean	Std Dev	Mean	Std Dev
1	78	-14.0641026	13.3039783	35.6410256	11.4551348
2	72	-10.0416667	11.5300434	34.1805556	13.2157891
3	77	-10.4285714	11.0005126	36.7662338	10.2017750
900	80	-9.2500000	12.0793788	35.2625000	10.5826987

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 PROTOCOL 331-201-00061

4 OF 6

Proc GLM Output for Change [REDACTED] in CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT Analysis Visit (N)=10 -----

The GLM Procedure
 Least Squares Means

TRTPN	CHG LSMEAN	Standard Error	Pr > t	LSMEAN Number
1	-14.2497820	1.3315680	<.0001	1
2	-10.7317336	1.4251581	<.0001	2
3	-9.8128458	1.3613721	<.0001	3
900	-9.3462805	1.3329065	<.0001	4

Least Squares Means for effect TRTPN
 Pr > |t| for H0: LSMean(i)=LSMean(j)

Dependent Variable: CHG

i/j	1	2	3	4
1		0.0526	0.0131	0.0055
2	0.0526		0.6138	0.4402
3	0.0131	0.6138		0.7912
4	0.0055	0.4402	0.7912	

SOURCE: GLMOUT; TABLE: stat1b.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.2 FINAL

BREXPIRAZOLE
 PROTOCOL 331-201-00061

5 OF 6

Proc GLM Output for Change [REDACTED] in CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT Analysis Visit (N)=10 -----				
The GLM Procedure				
Least Squares Means				
TRTPN	CHG	LSMEAN	95% Confidence Limits	
1		-14.249782	-16.870469	-11.629095
2		-10.731734	-13.536618	-7.926849
3		-9.812846	-12.492191	-7.133500
900		-9.346281	-11.969602	-6.722959
Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-3.518048	-7.076422	0.040325
1	3	-4.436936	-7.934242	-0.939630
1	4	-4.903501	-8.352735	-1.454268
2	3	-0.918888	-4.498991	2.661216
2	4	-1.385453	-4.912988	2.142082
3	4	-0.466565	-3.931224	2.998093

NOTE: To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

SOURCE: GLMOUT; TABLE: stat1b.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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6 OF 6

STAT-4.2
Proc GLM Output for Change [REDACTED] in CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT Analysis Visit (N)=10 -----

The GLM Procedure
Dependent Variable: CHG Change from Baseline

Parameter	Estimate	Standard Error	t Value	Pr > t
1 vs 900	-4.90350146	1.75255116	-2.80	0.0055
1 vs 3	-4.43693620	1.77697680	-2.50	0.0131
1 vs 2	-3.51804843	1.80800508	-1.95	0.0526
2 vs 900	-1.38545304	1.79233627	-0.77	0.4402
3 vs 900	-0.46656526	1.76038849	-0.27	0.7912

SOURCE: GLMOUT; TABLE: stat1b.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIRAZOLE
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1 OF 6

STAT-4.3
Proc GLM Output for Change [REDACTED] in CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT Analysis Visit (N)=10 -----

The GLM Procedure
Class Level Information
Class Levels Values
TRTPN 4 1 2 3 900

Number of Observations Read 307
Number of Observations Used 307

SOURCE: GLMOUT; TABLE: stat1c.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.3 FINAL

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BREXPIRAZOLE
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2 OF 6

Proc GLM Output for Change STAT=4.3 in CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT Analysis Visit (N)=10 -----					
The GLM Procedure					
Dependent Variable: CHG Change from Baseline					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	4	7566.86549	1891.71637	15.32	<.0001
Error	302	37292.49607	123.48509		
Corrected Total	306	44859.36156			
R-Square Coeff Var Root MSE CHG Mean					
0.168680 -101.4422 11.11238 -10.95440					
Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRTPN	3	1027.098016	342.366005	2.77	0.0417
BASE	1	6498.915555	6498.915555	52.63	<.0001

SOURCE: GLMOUT; TABLE: stat1c.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.3 FINAL

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BREXPIRAZOLE
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STAT=4.3
Proc GLM Output for Change [REDACTED] in CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT Analysis Visit (N)=10 -----

The GLM Procedure

Level of		-----CHG-----		-----BASE-----	
TRTPN	N	Mean	Std Dev	Mean	Std Dev
1	78	-14.0641026	13.3039783	35.6410256	11.4551348
2	72	-10.0416667	11.5300434	34.1805556	13.2157891
3	77	-10.4285714	11.0005126	36.7662338	10.2017750
900	80	-9.2500000	12.0793788	35.2625000	10.5826987

SOURCE: GLMOUT; TABLE: stat1c.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.3 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

4 OF 6

STAT-4.3
 Proc GLM Output for Change [REDACTED] in CAPS-5 Total Score, OC
 (Intent to Treat Sample)

 ----- Parameter Code=CAPSTOT Analysis Visit (N)=10 -----

The GLM Procedure
 Least Squares Means

TRTPN	CHG LSMEAN	Standard Error	Pr > t	LSMEAN Number
1	-13.9994374	1.2582613	<.0001	1
2	-10.5711945	1.3116396	<.0001	2
3	-9.9061147	1.2684199	<.0001	3
900	-9.3393381	1.2424634	<.0001	4

Least Squares Means for effect TRTPN
 Pr > |t| for H0: LSMean(i)=LSMean(j)

Dependent Variable: CHG

i/j	1	2	3	4
1		0.0603	0.0226	0.0088
2	0.0603		0.7162	0.4957
3	0.0226	0.7162		0.7499
4	0.0088	0.4957	0.7499	

SOURCE: GLMOUT; TABLE: stat1c.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIRAZOLE
 PROTOCOL 331-201-00061

5 OF 6

Proc GLM Output for Change [REDACTED] in CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT Analysis Visit (N)=10 -----				
The GLM Procedure				
Least Squares Means				
TRTPN	CHG	LSMEAN	95% Confidence Limits	
1		-13.999437	-16.475507	-11.523367
2		-10.571194	-13.152305	-7.990084
3		-9.906115	-12.402175	-7.410054
900		-9.339338	-11.784320	-6.894356
Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-3.428243	-7.005685	0.149199
1	3	-4.093323	-7.608471	-0.578174
1	4	-4.660099	-8.140000	-1.180199
2	3	-0.665080	-4.261350	2.931190
2	4	-1.231856	-4.786164	2.322452
3	4	-0.566777	-4.061790	2.928237

NOTE: To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

SOURCE: GLMOUT; TABLE: stat1c.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIRAZOLE
PROTOCOL 331-201-00061

6 OF 6

STAT-4.3
Proc GLM Output for Change [REDACTED] in CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT Analysis Visit (N)=10 -----

The GLM Procedure
Dependent Variable: CHG Change from Baseline

Parameter	Estimate	Standard Error	t Value	Pr > t
1 vs 900	-4.66009920	1.76837676	-2.64	0.0088
1 vs 3	-4.09332267	1.78628851	-2.29	0.0226
1 vs 2	-3.42824286	1.81794426	-1.89	0.0603
2 vs 900	-1.23185635	1.80618824	-0.68	0.4957
3 vs 900	-0.56677654	1.77605684	-0.32	0.7499

SOURCE: GLMOUT; TABLE: stat1c.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIRAZOLE
PROTOCOL 331-201-00061

1 OF 2

STAT-4.4
Proc GLM Output for Treatment by Center Interaction [REDACTED] in CAPS-5 Total Score, LOCF
(Intent to Treat Sa

----- Parameter Code=CAPSTOT Analysis Visit (N)=10 -----
The GLM Procedure
Class Level Information

Class	Levels	Values
TRTPN	4	1 2 3 900
POOLCNTR	10	[REDACTED]
COMBFL	2	N Y

Number of Observations Read 307
Number of Observations Used 307

SOURCE: GLMCNTR; TABLE: statld.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIRAZOLE
 PROTOCOL 331-201-00061

2 OF 2

STAT-4.4
 Proc GLM Output for Treatment by Center Interaction [REDACTED] in CAPS-5 Total Score, LOCF
 (Intent to Treat Sa

 ----- Parameter Code=CAPSTOT Analysis Visit (N)=10 -----

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	41	11141.84874	271.75241	2.14	0.0002
Error	265	33717.51282	127.23590		
Corrected Total	306	44859.36156			

R-Square	Coeff Var	Root MSE	CHG Mean
0.248373	-102.9713	11.27989	-10.95440

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRTPN	3	972.107649	324.035883	2.55	0.0564
POOLCNTR	9	1863.926540	207.102949	1.63	0.1073
TRTPN*POOLCNTR	27	1550.713857	57.433847	0.45	0.9922
COMBFL	1	13.706100	13.706100	0.11	0.7430
BASE	1	5385.659316	5385.659316	42.33	<.0001

SOURCE: GLMCNTR; TABLE: statld.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIRAZOLE
 PROTOCOL 331-201-00061

1 OF 3

Summary of Mean Change [REDACTED] in CAPS-5 Total Score
 By Center - LOCF (Intent to Treat Sample)

CENTER	CAPS-5 TOTAL SCORE								TREATMENT COMPARISON	LS MEAN DIFFERENCE ¹
	BREX+SERT		BREX		SERT		PLACEBO			
	N	LS MEAN (SE)	N	LS MEAN (SE)	N	LS MEAN (SE)	N	LS MEAN (SE)		
OVERALL	78	-14.2 (1.33)	72	-10.7 (1.43)	77	-9.81 (1.36)	80	-9.35 (1.33)	BREX+SERT VS. BREX	-3.52 (-7.08, 0.04)
									BREX+SERT VS. SERT	-4.44 (-7.93, -0.94)
									BREX+SERT VS. PLACEBO	-4.90 (-8.35, -1.45)
									BREX VS. PLACEBO	-1.39 (-4.91, 2.14)
									SERT VS. PLACEBO	-0.47 (-3.93, 3.00)
	4	-8.36 (5.65)	3	-14.0 (6.52)	3	-4.00 (6.52)	3	-10.8 (6.52)	BREX+SERT VS. BREX	5.60 (-11.4, 22.60)
									BREX+SERT VS. SERT	-4.37 (-21.3, 12.61)
									BREX+SERT VS. PLACEBO	2.43 (-14.5, 19.40)
									BREX VS. PLACEBO	-3.17 (-21.3, 14.98)
									SERT VS. PLACEBO	6.79 (-11.3, 24.93)
	4	-15.0 (5.66)	4	-4.30 (5.66)	3	-9.06 (6.52)	4	-10.6 (5.66)	BREX+SERT VS. BREX	-10.7 (-26.4, 5.05)
									BREX+SERT VS. SERT	-5.89 (-22.9, 11.07)
									BREX+SERT VS. PLACEBO	-4.35 (-20.1, 11.35)
									BREX VS. PLACEBO	6.30 (-9.40, 22.01)
									SERT VS. PLACEBO	1.54 (-15.4, 18.51)
	7	-12.1 (4.34)	8	-10.8 (4.04)	7	-15.9 (4.33)	7	-8.01 (4.30)	BREX+SERT VS. BREX	-1.28 (-12.8, 10.23)
									BREX+SERT VS. SERT	3.82 (-8.05, 15.69)
									BREX+SERT VS. PLACEBO	-4.08 (-16.0, 7.84)
									BREX VS. PLACEBO	-2.80 (-14.3, 8.70)
									SERT VS. PLACEBO	-7.90 (-19.8, 4.01)
	14	-12.3 (3.12)	13	-8.20 (3.22)	16	-6.02 (2.87)	15	-6.81 (2.98)	BREX+SERT VS. BREX	-4.14 (-12.7, 4.42)
								BREX+SERT VS. SERT	-6.32 (-14.5, 1.83)	

1

FILE: centera.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/center.sas
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BREXPIRAZOLE
 PROTOCOL 331-201-00061

2 OF 3

Summary of Mean Change [REDACTED] in CAPS-5 Total Score
 By Center - LOCF (Intent to Treat Sample)

CENTER	CAPS-5 TOTAL SCORE								TREATMENT COMPARISON	LS MEAN DIFFERENCE ¹
	BREX+SERT		BREX		SERT		PLACEBO			
	N	LS MEAN (SE)	N	LS MEAN (SE)	N	LS MEAN (SE)	N	LS MEAN (SE)		
	14	-12.3 (3.12)	13	-8.20 (3.22)	16	-6.02 (2.87)	15	-6.81 (2.98)	BREX+SERT VS. PLACEBO	-5.53 (-13.8, 2.74)
	13	-10.6 (3.14)	9	-10.8 (3.82)	7	-9.05 (4.31)	10	-8.06 (3.62)	BREX VS. PLACEBO	-1.39 (-9.81, 7.04)
									SERT VS. PLACEBO	0.80 (-7.21, 8.80)
									BREX+SERT VS. BREX	0.21 (-9.51, 9.93)
									BREX+SERT VS. SERT	-1.58 (-12.0, 8.89)
	7	-14.6 (4.32)	10	-15.8 (3.63)	9	-9.98 (3.82)	9	-11.4 (3.79)	BREX+SERT VS. PLACEBO	-2.56 (-11.9, 6.82)
									BREX VS. PLACEBO	-2.77 (-13.0, 7.48)
									SERT VS. PLACEBO	-0.99 (-11.9, 9.96)
									BREX+SERT VS. BREX	1.17 (-9.79, 12.14)
	9	-16.2 (3.77)	8	-7.83 (4.02)	8	-10.5 (4.05)	10	-7.91 (3.58)	BREX+SERT VS. SERT	-4.63 (-15.8, 6.56)
									BREX+SERT VS. PLACEBO	-3.22 (-14.4, 8.01)
									BREX VS. PLACEBO	-4.39 (-14.6, 5.82)
									SERT VS. PLACEBO	1.42 (-9.08, 11.91)
									BREX+SERT VS. BREX	-8.36 (-19.2, 2.47)
									BREX+SERT VS. SERT	-5.73 (-16.6, 5.14)
									BREX+SERT VS. PLACEBO	-8.28 (-18.5, 1.94)
BREX VS. PLACEBO									0.08 (-10.5, 10.62)	
								SERT VS. PLACEBO	-2.55 (-13.1, 8.01)	

¹

FILE: centera.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/center.sas
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BREXPIPAZOLE
 PROTOCOL 331-201-00061

3 OF 3

Summary of Mean Change [REDACTED] in CAPS-5 Total Score
 By Center - LOCF (Intent to Treat Sample)

CENTER	CAPS-5 TOTAL SCORE								TREATMENT COMPARISON	LS MEAN DIFFERENCE ¹
	BREX+SERT		BREX		SERT		PLACEBO			
	N	LS MEAN (SE)	N	LS MEAN (SE)	N	LS MEAN (SE)	N	LS MEAN (SE)		
	8	-20.6 (4.01)	6	-16.8 (4.64)	11	-16.3 (3.44)	10	-14.0 (3.64)	BREX+SERT VS. BREX	-3.81 (-15.8, 8.19)
									BREX+SERT VS. SERT	-4.29 (-14.6, 6.04)
									BREX+SERT VS. PLACEBO	-6.60 (-17.2, 3.96)
									BREX VS. PLACEBO	-2.78 (-14.3, 8.69)
									SERT VS. PLACEBO	-2.31 (-12.1, 7.44)
	7	-13.9 (4.30)	7	-9.63 (4.37)	7	-12.5 (4.27)	7	-12.0 (4.32)	BREX+SERT VS. BREX	-4.30 (-16.3, 7.68)
									BREX+SERT VS. SERT	-1.42 (-13.3, 10.49)
									BREX+SERT VS. PLACEBO	-1.87 (-13.8, 10.08)
									BREX VS. PLACEBO	2.42 (-9.46, 14.31)
									SERT VS. PLACEBO	-0.45 (-12.4, 11.52)
	5	-20.8 (5.07)	4	-9.09 (5.66)	6	-4.10 (4.61)	5	-8.00 (5.09)	BREX+SERT VS. BREX	-11.7 (-26.6, 3.22)
									BREX+SERT VS. SERT	-16.7 (-30.1, -3.22)
								BREX+SERT VS. PLACEBO	-12.8 (-26.9, 1.33)	
								BREX VS. PLACEBO	-1.09 (-16.0, 13.83)	
								SERT VS. PLACEBO	3.89 (-9.61, 17.40)	

¹

FILE: centera.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/center.sas
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 PROTOCOL 331-201-00061

1 OF 1

STAT-4.5.2
 Differences in Unadjusted Mean Changes of CAPS-5 Total Score [REDACTED] Among Treatment Groups
 By Center - LOCF (Intent to Treat)

CENTER	COUNTRY	BREX+SERT		BREX		SERT		PLACEBO		BREX+SERT VS. PLACEBO	BREX+SERT VS. SERT	BREX+SERT VS. BREX	BREX VS. P LACEBO	SERT vs. P LACEBO
		N	MEAN ¹	N	MEAN ¹	N	MEAN ¹	N	MEAN ¹	DIFF ²	DIFF ²	DIFF ²	DIFF ²	DIFF ²
[REDACTED]	USA	5	-21.80	4	-8.25	6	-4.83	5	-4.80	-17.00	-16.97	-13.55	-3.45	-0.03
	USA	9	-15.00	8	-9.38	8	-13.00	10	-8.70	-6.30	-2.00	-5.63	-0.68	-4.30
	USA	7	-14.29	7	-4.71	7	-13.43	7	-8.14	-6.14	-0.86	-9.57	3.43	-5.29
	USA	7	-16.71	10	-15.90	9	-11.56	9	-10.78	-5.94	-5.16	-0.81	-5.12	-0.78
	USA	14	-10.14	13	-6.31	16	-5.63	15	-4.53	-5.61	-4.52	-3.84	-1.77	-1.09
	USA	8	-21.13	6	-18.50	11	-15.45	10	-16.10	-5.02	-5.67	-2.63	-2.40	0.65
	USA	4	-16.75	4	-6.50	3	-10.67	4	-12.50	-4.25	-6.08	-10.25	6.00	1.83
	USA	13	-12.00	9	-10.11	7	-10.57	10	-10.30	-1.70	-1.43	-1.89	0.19	-0.27
	USA	7	-8.57	8	-9.25	7	-12.86	7	-7.86	-0.71	4.29	0.68	-1.39	-5.00
	USA	4	-10.50	3	-13.00	3	-5.33	3	-12.67	2.17	-5.17	2.50	-0.33	7.33

¹ [REDACTED]

FILE: centerb.lis, RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/center.sas
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 PROTOCOL 331-201-00061

1 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	75	-5.9467	10.8539	1.2533	-33.0000	36.0000
900	80	-5.6250	9.6527	1.0792	-37.0000	12.0000
Diff (1-2)		-0.3217	10.2513	1.6477		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-5.9467	-8.4439 -3.4494	10.8539	9.3520 12.9352
900		-5.6250	-7.7731 -3.4769	9.6527	8.3539 11.4333
Diff (1-2)	Pooled	-0.3217	-3.5768 2.9334	10.2513	9.2200 11.5443
Diff (1-2)	Satterthwaite	-0.3217	-3.5900 2.9467		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	153	-0.20	0.8455
Satterthwaite	Unequal	148.13	-0.19	0.8461

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIRAZOLE
PROTOCOL 331-201-00061

2 OF 40

STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	74	79	1.26	0.3055

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

3 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	78	-10.5769	12.3357	1.3967	-47.0000	23.0000
900	80	-8.0500	11.1252	1.2438	-33.0000	24.0000
Diff (1-2)		-2.5269	11.7383	1.8678		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-10.5769	-13.3582 -7.7957	12.3357	10.6575 14.6460
900		-8.0500	-10.5258 -5.5742	11.1252	9.6283 13.1775
Diff (1-2)	Pooled	-2.5269	-6.2165 1.1626	11.7383	10.5677 13.2028
Diff (1-2)	Satterthwaite	-2.5269	-6.2218 1.1679		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	156	-1.35	0.1781
Satterthwaite	Unequal	153.48	-1.35	0.1787

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIRAZOLE
PROTOCOL 331-201-00061

4 OF 40

STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	77	79	1.23	0.3629

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

5 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	78	-14.0641	13.3040	1.5064	-47.0000	15.0000
900	80	-9.2500	12.0794	1.3505	-45.0000	13.0000
Diff (1-2)		-4.8141	12.6986	2.0207		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-14.0641	-17.0637 -11.0645	13.3040	11.4941 15.7957
900		-9.2500	-11.9381 -6.5619	12.0794	10.4541 14.3077
Diff (1-2)	Pooled	-4.8141	-8.8055 -0.8227	12.6986	11.4323 14.2829
Diff (1-2)	Satterthwaite	-4.8141	-8.8108 -0.8174		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	156	-2.38	0.0184
Satterthwaite	Unequal	153.73	-2.38	0.0186

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	77	79	1.21	0.3949

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	78	-14.7308	13.0908	1.4822	-47.0000	18.0000
900	80	-10.0875	13.3892	1.4970	-43.0000	18.0000
Diff (1-2)		-4.6433	13.2427	2.1072		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-14.7308	-17.6823 -11.7793	13.0908	11.3099 15.5425
900		-10.0875	-13.0671 -7.1079	13.3892	11.5877 15.8591
Diff (1-2)	Pooled	-4.6433	-8.8057 -0.4809	13.2427	11.9221 14.8949
Diff (1-2)	Satterthwaite	-4.6433	-8.8045 -0.4821		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	156	-2.20	0.0290
Satterthwaite	Unequal	156	-2.20	0.0290

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	79	77	1.05	0.8435

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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Unadjusted Mean Change XXXXXXXXXX STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	75	-5.9467	10.8539	1.2533	-33.0000	36.0000
3	76	-6.0132	8.6217	0.9890	-33.0000	17.0000
Diff (1-2)		0.0665	9.7941	1.5941		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-5.9467	-8.4439 -3.4494	10.8539	9.3520 12.9352
3		-6.0132	-7.9833 -4.0430	8.6217	7.4354 10.2618
Diff (1-2)	Pooled	0.0665	-3.0835 3.2165	9.7941	8.7971 11.0480
Diff (1-2)	Satterthwaite	0.0665	-3.0897 3.2227		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	149	0.04	0.9668
Satterthwaite	Unequal	140.93	0.04	0.9668

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	74	75	1.58	0.0484

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

11 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	78	-10.5769	12.3357	1.3967	-47.0000	23.0000
3	77	-8.8701	10.1390	1.1554	-46.0000	12.0000
Diff (1-2)		-1.7068	11.2980	1.8150		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-10.5769	-13.3582 -7.7957	12.3357	10.6575 14.6460
3		-8.8701	-11.1714 -6.5689	10.1390	8.7519 12.0526
Diff (1-2)	Pooled	-1.7068	-5.2925 1.8789	11.2980	10.1615 12.7230
Diff (1-2)	Satterthwaite	-1.7068	-5.2889 1.8753		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	153	-0.94	0.3485
Satterthwaite	Unequal	148.15	-0.94	0.3479

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	77	76	1.48	0.0886

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	78	-14.0641	13.3040	1.5064	-47.0000	15.0000
3	77	-10.4286	11.0005	1.2536	-38.0000	12.0000
Diff (1-2)		-3.6355	12.2142	1.9622		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-14.0641	-17.0637 -11.0645	13.3040	11.4941 15.7957
3		-10.4286	-12.9254 -7.9318	11.0005	9.4956 13.0768
Diff (1-2)	Pooled	-3.6355	-7.5120 0.2409	12.2142	10.9855 13.7548
Diff (1-2)	Satterthwaite	-3.6355	-7.5082 0.2371		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	153	-1.85	0.0658
Satterthwaite	Unequal	148.45	-1.86	0.0656

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	77	76	1.46	0.0987

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIPIRAZOLE STAT-4.6 FINAL

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BREXPIRAZOLE
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Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	78	-14.7308	13.0908	1.4822	-47.0000	18.0000
3	77	-13.1558	12.3257	1.4046	-50.0000	12.0000
Diff (1-2)		-1.5749	12.7165	2.0429		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-14.7308	-17.6823 -11.7793	13.0908	11.3099 15.5425
3		-13.1558	-15.9534 -10.3583	12.3257	10.6395 14.6521
Diff (1-2)	Pooled	-1.5749	-5.6108 2.4609	12.7165	11.4373 14.3204
Diff (1-2)	Satterthwaite	-1.5749	-5.6093 2.4594		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	153	-0.77	0.4419
Satterthwaite	Unequal	152.66	-0.77	0.4418

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	77	76	1.13	0.6001

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIPIRAZOLE STAT-4.6 FINAL

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Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	75	-5.9467	10.8539	1.2533	-33.0000	36.0000
2	67	-3.3731	8.7019	1.0631	-24.0000	17.0000
Diff (1-2)		-2.5735	9.8979	1.6639		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-5.9467	-8.4439 -3.4494	10.8539	9.3520 12.9352
2		-3.3731	-5.4957 -1.2506	8.7019	7.4374 10.4883
Diff (1-2)	Pooled	-2.5735	-5.8631 0.7160	9.8979	8.8618 11.2104
Diff (1-2)	Satterthwaite	-2.5735	-5.8231 0.6760		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	140	-1.55	0.1242
Satterthwaite	Unequal	138.44	-1.57	0.1196

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	74	66	1.56	0.0688

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIPIRAZOLE STAT-4.6 FINAL

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Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	78	-10.5769	12.3357	1.3967	-47.0000	23.0000
2	72	-6.0694	11.3960	1.3430	-29.0000	29.0000
Diff (1-2)		-4.5075	11.8942	1.9439		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-10.5769	-13.3582 -7.7957	12.3357	10.6575 14.6460
2		-6.0694	-8.7474 -3.3915	11.3960	9.7908 13.6356
Diff (1-2)	Pooled	-4.5075	-8.3488 -0.6662	11.8942	10.6797 13.4227
Diff (1-2)	Satterthwaite	-4.5075	-8.3366 -0.6784		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	148	-2.32	0.0218
Satterthwaite	Unequal	148	-2.33	0.0214

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	77	71	1.17	0.5000

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	78	-14.0641	13.3040	1.5064	-47.0000	15.0000
2	72	-10.0417	11.5300	1.3588	-37.0000	29.0000
Diff (1-2)		-4.0224	12.4845	2.0403		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-14.0641	-17.0637 -11.0645	13.3040	11.4941 15.7957
2		-10.0417	-12.7511 -7.3322	11.5300	9.9060 13.7960
Diff (1-2)	Pooled	-4.0224	-8.0544 0.00952	12.4845	11.2098 14.0889
Diff (1-2)	Satterthwaite	-4.0224	-8.0315 -0.0134		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	148	-1.97	0.0505
Satterthwaite	Unequal	147.43	-1.98	0.0493

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	77	71	1.33	0.2231

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	78	-14.7308	13.0908	1.4822	-47.0000	18.0000
2	72	-9.8611	12.7537	1.5030	-40.0000	29.0000
Diff (1-2)		-4.8697	12.9302	2.1132		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-14.7308	-17.6823 -11.7793	13.0908	11.3099 15.5425
2		-9.8611	-12.8581 -6.8641	12.7537	10.9573 15.2601
Diff (1-2)	Pooled	-4.8697	-9.0456 -0.6938	12.9302	11.6099 14.5918
Diff (1-2)	Satterthwaite	-4.8697	-9.0413 -0.6980		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	148	-2.30	0.0226
Satterthwaite	Unequal	147.56	-2.31	0.0225

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	77	71	1.05	0.8257

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
2	67	-3.3731	8.7019	1.0631	-24.0000	17.0000
900	80	-5.6250	9.6527	1.0792	-37.0000	12.0000
Diff (1-2)		2.2519	9.2320	1.5289		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
2		-3.3731	-5.4957 -1.2506	8.7019	7.4374 10.4883
900		-5.6250	-7.7731 -3.4769	9.6527	8.3539 11.4333
Diff (1-2)	Pooled	2.2519	-0.7699 5.2736	9.2320	8.2807 10.4322
Diff (1-2)	Satterthwaite	2.2519	-0.7424 5.2461		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	145	1.47	0.1429
Satterthwaite	Unequal	144.19	1.49	0.1393

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	79	66	1.23	0.3866

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
2	72	-6.0694	11.3960	1.3430	-29.0000	29.0000
900	80	-8.0500	11.1252	1.2438	-33.0000	24.0000
Diff (1-2)		1.9806	11.2542	1.8282		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
2		-6.0694	-8.7474 -3.3915	11.3960	9.7908 13.6356
900		-8.0500	-10.5258 -5.5742	11.1252	9.6283 13.1775
Diff (1-2)	Pooled	1.9806	-1.6318 5.5929	11.2542	10.1120 12.6896
Diff (1-2)	Satterthwaite	1.9806	-1.6369 5.5980		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	150	1.08	0.2804
Satterthwaite	Unequal	147.5	1.08	0.2810

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	71	79	1.05	0.8325

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
2	72	-10.0417	11.5300	1.3588	-37.0000	29.0000
900	80	-9.2500	12.0794	1.3505	-45.0000	13.0000
Diff (1-2)		-0.7917	11.8225	1.9205		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
2		-10.0417	-12.7511 -7.3322	11.5300	9.9060 13.7960
900		-9.2500	-11.9381 -6.5619	12.0794	10.4541 14.3077
Diff (1-2)	Pooled	-0.7917	-4.5865 3.0031	11.8225	10.6227 13.3304
Diff (1-2)	Satterthwaite	-0.7917	-4.5772 2.9939		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	150	-0.41	0.6808
Satterthwaite	Unequal	149.47	-0.41	0.6800

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	79	71	1.10	0.6916

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIPIRAZOLE STAT-4.6 FINAL

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Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
2	72	-9.8611	12.7537	1.5030	-40.0000	29.0000
900	80	-10.0875	13.3892	1.4970	-43.0000	18.0000
Diff (1-2)		0.2264	13.0922	2.1268		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
2		-9.8611	-12.8581 -6.8641	12.7537	10.9573 15.2601
900		-10.0875	-13.0671 -7.1079	13.3892	11.5877 15.8591
Diff (1-2)	Pooled	0.2264	-3.9759 4.4287	13.0922	11.7635 14.7621
Diff (1-2)	Satterthwaite	0.2264	-3.9653 4.4180		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	150	0.11	0.9154
Satterthwaite	Unequal	149.51	0.11	0.9152

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	79	71	1.10	0.6785

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIPIRAZOLE STAT-4.6 FINAL

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Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
3	76	-6.0132	8.6217	0.9890	-33.0000	17.0000
900	80	-5.6250	9.6527	1.0792	-37.0000	12.0000
Diff (1-2)		-0.3882	9.1651	1.4681		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
3		-6.0132	-7.9833 -4.0430	8.6217	7.4354 10.2618
900		-5.6250	-7.7731 -3.4769	9.6527	8.3539 11.4333
Diff (1-2)	Pooled	-0.3882	-3.2883 2.5120	9.1651	8.2458 10.3168
Diff (1-2)	Satterthwaite	-0.3882	-3.2800 2.5037		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	154	-0.26	0.7918
Satterthwaite	Unequal	153.43	-0.27	0.7912

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	79	75	1.25	0.3253

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
3	77	-8.8701	10.1390	1.1554	-46.0000	12.0000
900	80	-8.0500	11.1252	1.2438	-33.0000	24.0000
Diff (1-2)		-0.8201	10.6530	1.7007		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
3		-8.8701	-11.1714 -6.5689	10.1390	8.7519 12.0526
900		-8.0500	-10.5258 -5.5742	11.1252	9.6283 13.1775
Diff (1-2)	Pooled	-0.8201	-4.1797 2.5394	10.6530	9.5876 11.9869
Diff (1-2)	Satterthwaite	-0.8201	-4.1738 2.5336		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	155	-0.48	0.6303
Satterthwaite	Unequal	154.55	-0.48	0.6297

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	79	76	1.20	0.4169

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
3	77	-10.4286	11.0005	1.2536	-38.0000	12.0000
900	80	-9.2500	12.0794	1.3505	-45.0000	13.0000
Diff (1-2)		-1.1786	11.5630	1.8460		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
3		-10.4286	-12.9254 -7.9318	11.0005	9.4956 13.0768
900		-9.2500	-11.9381 -6.5619	12.0794	10.4541 14.3077
Diff (1-2)	Pooled	-1.1786	-4.8251 2.4680	11.5630	10.4066 13.0108
Diff (1-2)	Satterthwaite	-1.1786	-4.8187 2.4615		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	155	-0.64	0.5241
Satterthwaite	Unequal	154.53	-0.64	0.5234

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	79	76	1.21	0.4132

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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Unadjusted Mean Change [REDACTED] STAT-4.6
 Phase B by Study Week CAPS-5 Total Score, LOCF
 (Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
3	77	-13.1558	12.3257	1.4046	-50.0000	12.0000
900	80	-10.0875	13.3892	1.4970	-43.0000	18.0000
Diff (1-2)		-3.0683	12.8787	2.0560		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
3		-13.1558	-15.9534 -10.3583	12.3257	10.6395 14.6521
900		-10.0875	-13.0671 -7.1079	13.3892	11.5877 15.8591
Diff (1-2)	Pooled	-3.0683	-7.1298 0.9931	12.8787	11.5907 14.4913
Diff (1-2)	Satterthwaite	-3.0683	-7.1234 0.9868		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	155	-1.49	0.1376
Satterthwaite	Unequal	154.7	-1.49	0.1370

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.6
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, LOCF
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	79	76	1.18	0.4692

SOURCE: TTESTLOCF; TABLE: stat1h.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.6 FINAL

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 PROTOCOL 331-201-00061

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Unadjusted Mean Change [REDACTED] STAT-4.7 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	74	-6.0135	10.9125	1.2685	-33.0000	36.0000
900	77	-5.6623	9.7732	1.1138	-37.0000	12.0000
Diff (1-2)		-0.3512	10.3471	1.6844		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-6.0135	-8.5417 -3.4853	10.9125	9.3936 13.0219
900		-5.6623	-7.8806 -3.4441	9.7732	8.4362 11.6179
Diff (1-2)	Pooled	-0.3512	-3.6796 2.9772	10.3471	9.2938 11.6717
Diff (1-2)	Satterthwaite	-0.3512	-3.6875 2.9851		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	149	-0.21	0.8351
Satterthwaite	Unequal	145.74	-0.21	0.8355

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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BREXPIRAZOLE
PROTOCOL 331-201-00061

2 OF 40

STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	73	76	1.25	0.3423

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

3 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.7
 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	64	-11.5469	12.9123	1.6140	-47.0000	23.0000
900	70	-7.7571	11.1205	1.3292	-29.0000	24.0000
Diff (1-2)		-3.7897	12.0091	2.0769		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-11.5469	-14.7723 -8.3215	12.9123	10.9987 15.6384
900		-7.7571	-10.4087 -5.1056	11.1205	9.5349 13.3435
Diff (1-2)	Pooled	-3.7897	-7.8981 0.3186	12.0091	10.7187 13.6555
Diff (1-2)	Satterthwaite	-3.7897	-7.9279 0.3484		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	132	-1.82	0.0703
Satterthwaite	Unequal	124.95	-1.81	0.0723

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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4 OF 40

STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	63	69	1.35	0.2255

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

5 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.7 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	59	-15.4237	14.2178	1.8510	-47.0000	15.0000
900	62	-9.6935	12.3919	1.5738	-45.0000	13.0000
Diff (1-2)		-5.7302	13.3132	2.4213		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-15.4237	-19.1289 -11.7186	14.2178	12.0358 17.3735
900		-9.6935	-12.8405 -6.5466	12.3919	10.5302 15.0596
Diff (1-2)	Pooled	-5.7302	-10.5246 -0.9357	13.3132	11.8153 15.2494
Diff (1-2)	Satterthwaite	-5.7302	-10.5427 -0.9176		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	119	-2.37	0.0196
Satterthwaite	Unequal	115.02	-2.36	0.0200

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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6 OF 40

STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	58	61	1.32	0.2904

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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BREXPIRAZOLE
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7 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.7
 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	57	-16.7193	13.7643	1.8231	-47.0000	18.0000
900	61	-11.1148	13.6920	1.7531	-43.0000	18.0000
Diff (1-2)		-5.6045	13.7269	2.5288		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-16.7193	-20.3715 -13.0671	13.7643	11.6206 16.8853
900		-11.1148	-14.6214 -7.6081	13.6920	11.6205 16.6691
Diff (1-2)	Pooled	-5.6045	-10.6131 -0.5960	13.7269	12.1650 15.7527
Diff (1-2)	Satterthwaite	-5.6045	-10.6143 -0.5948		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	116	-2.22	0.0286
Satterthwaite	Unequal	115.37	-2.22	0.0287

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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BREXPIRAZOLE
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STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	56	60	1.01	0.9657

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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Unadjusted Mean Change [REDACTED] STAT-4.7
 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	74	-6.0135	10.9125	1.2685	-33.0000	36.0000
3	74	-6.0405	8.7358	1.0155	-33.0000	17.0000
Diff (1-2)		0.0270	9.8842	1.6250		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-6.0135	-8.5417 -3.4853	10.9125	9.3936 13.0219
3		-6.0405	-8.0645 -4.0166	8.7358	7.5198 10.4244
Diff (1-2)	Pooled	0.0270	-3.1844 3.2385	9.8842	8.8688 11.1642
Diff (1-2)	Satterthwaite	0.0270	-3.1857 3.2398		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	146	0.02	0.9868
Satterthwaite	Unequal	139.33	0.02	0.9868

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	73	73	1.56	0.0592

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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Unadjusted Mean Change [REDACTED] STAT-4.7
 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	64	-11.5469	12.9123	1.6140	-47.0000	23.0000
3	62	-9.3387	10.4394	1.3258	-46.0000	11.0000
Diff (1-2)		-2.2082	11.7610	2.0958		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-11.5469	-14.7723 -8.3215	12.9123	10.9987 15.6384
3		-9.3387	-11.9898 -6.6876	10.4394	8.8710 12.6867
Diff (1-2)	Pooled	-2.2082	-6.3563 1.9399	11.7610	10.4616 13.4317
Diff (1-2)	Satterthwaite	-2.2082	-6.3437 1.9274		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	124	-1.05	0.2941
Satterthwaite	Unequal	120.19	-1.06	0.2926

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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12 OF 40

STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	63	61	1.53	0.0974

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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13 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.7 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	59	-15.4237	14.2178	1.8510	-47.0000	15.0000
3	58	-11.3448	9.9852	1.3111	-38.0000	10.0000
Diff (1-2)		-4.0789	12.3032	2.2750		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-15.4237	-19.1289 -11.7186	14.2178	12.0358 17.3735
3		-11.3448	-13.9703 -8.7194	9.9852	8.4415 12.2250
Diff (1-2)	Pooled	-4.0789	-8.5851 0.4273	12.3032	10.8979 14.1279
Diff (1-2)	Satterthwaite	-4.0789	-8.5770 0.4192		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	115	-1.79	0.0756
Satterthwaite	Unequal	104.13	-1.80	0.0750

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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14 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.7
Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	58	57	2.03	0.0083

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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Unadjusted Mean Change [REDACTED] STAT-4.7 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	57	-16.7193	13.7643	1.8231	-47.0000	18.0000
3	58	-15.0517	11.7852	1.5475	-50.0000	12.0000
Diff (1-2)		-1.6676	12.8043	2.3881		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-16.7193	-20.3715 -13.0671	13.7643	11.6206 16.8853
3		-15.0517	-18.1505 -11.9530	11.7852	9.9633 14.4288
Diff (1-2)	Pooled	-1.6676	-6.3988 3.0637	12.8043	11.3304 14.7225
Diff (1-2)	Satterthwaite	-1.6676	-6.4067 3.0716		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	113	-0.70	0.4864
Satterthwaite	Unequal	109.78	-0.70	0.4871

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	56	57	1.36	0.2458

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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Unadjusted Mean Change [REDACTED] STAT-4.7 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	74	-6.0135	10.9125	1.2685	-33.0000	36.0000
2	66	-3.3182	8.7568	1.0779	-24.0000	17.0000
Diff (1-2)		-2.6953	9.9554	1.6855		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-6.0135	-8.5417 -3.4853	10.9125	9.3936 13.0219
2		-3.3182	-5.4709 -1.1655	8.7568	7.4761 10.5711
Diff (1-2)	Pooled	-2.6953	-6.0281 0.6375	9.9554	8.9067 11.2864
Diff (1-2)	Satterthwaite	-2.6953	-5.9872 0.5965		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	138	-1.60	0.1121
Satterthwaite	Unequal	136.53	-1.62	0.1077

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	73	65	1.55	0.0720

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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 PROTOCOL 331-201-00061

19 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.7 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	64	-11.5469	12.9123	1.6140	-47.0000	23.0000
2	58	-6.1724	11.5214	1.5128	-29.0000	29.0000
Diff (1-2)		-5.3745	12.2713	2.2247		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-11.5469	-14.7723 -8.3215	12.9123	10.9987 15.6384
2		-6.1724	-9.2018 -3.1430	11.5214	9.7402 14.1058
Diff (1-2)	Pooled	-5.3745	-9.7792 -0.9698	12.2713	10.8957 14.0475
Diff (1-2)	Satterthwaite	-5.3745	-9.7544 -0.9945		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	120	-2.42	0.0172
Satterthwaite	Unequal	119.97	-2.43	0.0166

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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20 OF 40

STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	63	57	1.26	0.3837

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

21 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.7 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	59	-15.4237	14.2178	1.8510	-47.0000	15.0000
2	48	-11.3750	10.1952	1.4715	-37.0000	7.0000
Diff (1-2)		-4.0487	12.5772	2.4447		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-15.4237	-19.1289 -11.7186	14.2178	12.0358 17.3735
2		-11.3750	-14.3354 -8.4146	10.1952	8.4872 12.7703
Diff (1-2)	Pooled	-4.0487	-8.8962 0.7987	12.5772	11.0820 14.5427
Diff (1-2)	Satterthwaite	-4.0487	-8.7382 0.6408		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	105	-1.66	0.1007
Satterthwaite	Unequal	103.48	-1.71	0.0899

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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BREXPIRAZOLE
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22 OF 40

STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	58	47	1.94	0.0199

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

23 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.7 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	57	-16.7193	13.7643	1.8231	-47.0000	18.0000
2	48	-10.7500	12.3779	1.7866	-40.0000	15.0000
Diff (1-2)		-5.9693	13.1498	2.5761		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
1		-16.7193	-20.3715 -13.0671	13.7643	11.6206 16.8853
2		-10.7500	-14.3442 -7.1558	12.3779	10.3042 15.5043
Diff (1-2)	Pooled	-5.9693	-11.0783 -0.8603	13.1498	11.5732 15.2277
Diff (1-2)	Satterthwaite	-5.9693	-11.0320 -0.9066		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	103	-2.32	0.0225
Satterthwaite	Unequal	102.53	-2.34	0.0213

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIPIRAZOLE
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24 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.7 Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	56	47	1.24	0.4568

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIPIRAZOLE STAT-4.7 FINAL

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

25 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.7
 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
2	66	-3.3182	8.7568	1.0779	-24.0000	17.0000
900	77	-5.6623	9.7732	1.1138	-37.0000	12.0000
Diff (1-2)		2.3442	9.3185	1.5631		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
2		-3.3182	-5.4709 -1.1655	8.7568	7.4761 10.5711
900		-5.6623	-7.8806 -3.4441	9.7732	8.4362 11.6179
Diff (1-2)	Pooled	2.3442	-0.7460 5.4344	9.3185	8.3462 10.5492
Diff (1-2)	Satterthwaite	2.3442	-0.7200 5.4083		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	141	1.50	0.1359
Satterthwaite	Unequal	140.71	1.51	0.1327

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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BREXPIRAZOLE
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STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	76	65	1.25	0.3648

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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BREXPIRAZOLE
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27 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.7
 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
2	58	-6.1724	11.5214	1.5128	-29.0000	29.0000
900	70	-7.7571	11.1205	1.3292	-29.0000	24.0000
Diff (1-2)		1.5847	11.3036	2.0070		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
2		-6.1724	-9.2018 -3.1430	11.5214	9.7402 14.1058
900		-7.7571	-10.4087 -5.1056	11.1205	9.5349 13.3435
Diff (1-2)	Pooled	1.5847	-2.3872 5.5566	11.3036	10.0636 12.8948
Diff (1-2)	Satterthwaite	1.5847	-2.4024 5.5719		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	126	0.79	0.4313
Satterthwaite	Unequal	119.93	0.79	0.4329

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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28 OF 40

STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	57	69	1.07	0.7741

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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29 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.7
 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
2	48	-11.3750	10.1952	1.4715	-37.0000	7.0000
900	62	-9.6935	12.3919	1.5738	-45.0000	13.0000
Diff (1-2)		-1.6815	11.4877	2.2086		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
2		-11.3750	-14.3354 -8.4146	10.1952	8.4872 12.7703
900		-9.6935	-12.8405 -6.5466	12.3919	10.5302 15.0596
Diff (1-2)	Pooled	-1.6815	-6.0592 2.6963	11.4877	10.1387 13.2540
Diff (1-2)	Satterthwaite	-1.6815	-5.9524 2.5895		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	108	-0.76	0.4481
Satterthwaite	Unequal	107.57	-0.78	0.4369

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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30 OF 40

STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	61	47	1.48	0.1654

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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Unadjusted Mean Change [REDACTED] STAT-4.7 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
2	48	-10.7500	12.3779	1.7866	-40.0000	15.0000
900	61	-11.1148	13.6920	1.7531	-43.0000	18.0000
Diff (1-2)		0.3648	13.1310	2.5335		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
2		-10.7500	-14.3442 -7.1558	12.3779	10.3042 15.5043
900		-11.1148	-14.6214 -7.6081	13.6920	11.6205 16.6691
Diff (1-2)	Pooled	0.3648	-4.6577 5.3872	13.1310	11.5827 15.1608
Diff (1-2)	Satterthwaite	0.3648	-4.5984 5.3279		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	107	0.14	0.8858
Satterthwaite	Unequal	104.9	0.15	0.8844

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	60	47	1.22	0.4750

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIPIRAZOLE STAT-4.7 FINAL

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33 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.7 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
3	74	-6.0405	8.7358	1.0155	-33.0000	17.0000
900	77	-5.6623	9.7732	1.1138	-37.0000	12.0000
Diff (1-2)		-0.3782	9.2794	1.5106		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
3		-6.0405	-8.0645 -4.0166	8.7358	7.5198 10.4244
900		-5.6623	-7.8806 -3.4441	9.7732	8.4362 11.6179
Diff (1-2)	Pooled	-0.3782	-3.3632 2.6068	9.2794	8.3348 10.4674
Diff (1-2)	Satterthwaite	-0.3782	-3.3566 2.6002		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	149	-0.25	0.8026
Satterthwaite	Unequal	148.23	-0.25	0.8022

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	76	73	1.25	0.3361

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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Unadjusted Mean Change [REDACTED] STAT-4.7 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
3	62	-9.3387	10.4394	1.3258	-46.0000	11.0000
900	70	-7.7571	11.1205	1.3292	-29.0000	24.0000
Diff (1-2)		-1.5816	10.8063	1.8846		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
3		-9.3387	-11.9898 -6.6876	10.4394	8.8710 12.6867
900		-7.7571	-10.4087 -5.1056	11.1205	9.5349 13.3435
Diff (1-2)	Pooled	-1.5816	-5.3100 2.1469	10.8063	9.6372 12.3007
Diff (1-2)	Satterthwaite	-1.5816	-5.2958 2.1327		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	130	-0.84	0.4029
Satterthwaite	Unequal	129.55	-0.84	0.4011

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	69	61	1.13	0.6166

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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37 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.7
 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
3	58	-11.3448	9.9852	1.3111	-38.0000	10.0000
900	62	-9.6935	12.3919	1.5738	-45.0000	13.0000
Diff (1-2)		-1.6513	11.2936	2.0631		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
3		-11.3448	-13.9703 -8.7194	9.9852	8.4415 12.2250
900		-9.6935	-12.8405 -6.5466	12.3919	10.5302 15.0596
Diff (1-2)	Pooled	-1.6513	-5.7367 2.4341	11.2936	10.0182 12.9440
Diff (1-2)	Satterthwaite	-1.6513	-5.7085 2.4059		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	118	-0.80	0.4251
Satterthwaite	Unequal	115.51	-0.81	0.4218

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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BREXPIRAZOLE
PROTOCOL 331-201-00061

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STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	61	57	1.54	0.1015

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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39 OF 40

Unadjusted Mean Change [REDACTED] STAT-4.7 Phase B by Study Week CAPS-5 Total Score, OC
 (Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

TRTPN	N	Mean	Std Dev	Std Err	Minimum	Maximum
3	58	-15.0517	11.7852	1.5475	-50.0000	12.0000
900	61	-11.1148	13.6920	1.7531	-43.0000	18.0000
Diff (1-2)		-3.9370	12.7986	2.3472		

TRTPN	Method	Mean	95% CL Mean	Std Dev	95% CL Std Dev
3		-15.0517	-18.1505 -11.9530	11.7852	9.9633 14.4288
900		-11.1148	-14.6214 -7.6081	13.6920	11.6205 16.6691
Diff (1-2)	Pooled	-3.9370	-8.5855 0.7116	12.7986	11.3478 14.6781
Diff (1-2)	Satterthwaite	-3.9370	-8.5685 0.6945		

Method	Variances	DF	t Value	Pr > t
Pooled	Equal	117	-1.68	0.0962
Satterthwaite	Unequal	115.88	-1.68	0.0949

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.7 FINAL

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PROTOCOL 331-201-00061

40 OF 40

STAT-4.7
Unadjusted Mean Change [REDACTED] Phase B by Study Week CAPS-5 Total Score, OC
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The TTEST Procedure

Variable: CHG (Change from Baseline)

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	60	57	1.35	0.2560

SOURCE: TTESTOC; TABLE: statli.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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1 OF 4

STAT-4.8

Non-Parametric Stratified by Center and Type of Trauma Analysis of Mean Change [REDACTED] Phase B by Study Week in CAPS-5 Total
(Intent to Treat Sample)

Analysis Visit (N)=3 -----

The FREQ Procedure

Summary Statistics for TRTP by CHG
Controlling for POOLCNTR and COMBFL

Cochran-Mantel-Haenszel Statistics (Based on Rank Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	0.1690	0.6810
2	Row Mean Scores Differ	3	3.4071	0.3330

¹ WILCOXON TEST STRATIFIED BY (POOLED) CENTER AND TYPE OF TRAUMA.

SOURCE: NPAR; TABLE: statlj.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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2 OF 4

STAT-4.8

Non-Parametric Stratified by Center and Type of Trauma Analysis of Mean Change [REDACTED] Phase B by Study Week in CAPS-5 Total
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The FREQ Procedure

Summary Statistics for TRTP by CHG
Controlling for POOLCNTR and COMBFL

Cochran-Mantel-Haenszel Statistics (Based on Rank Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	1.0528	0.3049
2	Row Mean Scores Differ	3	2.6953	0.4410

¹ WILCOXON TEST STRATIFIED BY (POOLED) CENTER AND TYPE OF TRAUMA.

SOURCE: NPAR; TABLE: statlj.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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3 OF 4

STAT-4.8

Non-Parametric Stratified by Center and Type of Trauma Analysis of Mean Change [REDACTED] Phase B by Study Week in CAPS-5 Total
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The FREQ Procedure

Summary Statistics for TRTP by CHG
Controlling for POOLCNTR and COMBFL

Cochran-Mantel-Haenszel Statistics (Based on Rank Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	2.6378	0.1043
2	Row Mean Scores Differ	3	8.1432	0.0431

¹ WILCOXON TEST STRATIFIED BY (POOLED) CENTER AND TYPE OF TRAUMA.

SOURCE: NPAR; TABLE: statlj.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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4 OF 4

STAT-4.8

Non-Parametric Stratified by Center and Type of Trauma Analysis of Mean Change ██████████ Phase B by Study Week in CAPS-5 Total
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The FREQ Procedure

Summary Statistics for TRTP by CHG
Controlling for POOLCNTR and COMBFL

Cochran-Mantel-Haenszel Statistics (Based on Rank Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	0.0243	0.8762
2	Row Mean Scores Differ	3	6.6492	0.0840

1 WILCOXON TEST STRATIFIED BY (POOLED) CENTER AND TYPE OF TRAUMA.

SOURCE: NPAR; TABLE: statlj.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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1 OF 9

STAT-4.9
Residual [REDACTED] from Proc Mixed for Change from Baseline in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

The UNIVARIATE Procedure
Variable: RESID (Residual)
AVISITN = 10
AVISIT = [REDACTED]

Moments

N	227	Sum Weights	227
Mean	0.08611581	Sum Observations	19.5482882
Std Deviation	10.6826629	Variance	114.119287
Skewness	-0.1828243	Kurtosis	-0.146025
Uncorrected SS	25792.6423	Corrected SS	25790.9589
Coeff Variation	12404.9966	Std Error Mean	0.70903324

Basic Statistical Measures

Location		Variability	
Mean	0.08612	Std Deviation	10.68266
Median	-0.06010	Variance	114.11929
Mode	-5.59726	Range	58.82853
		Interquartile Range	14.39574

Note: The mode displayed is the smallest of 2 modes with a count of 2.

SOURCE: MMRMDX1; TABLE: statlk.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.9 FINAL

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2 OF 9

STAT-4.9
 Residual [REDACTED] from Proc Mixed for Change from Baseline in CAPS-5 Total Score, Primary Efficacy Analysis Model
 (Intent to Treat Sample)

The UNIVARIATE Procedure
 Variable: RESID (Residual)
 AVISITN = 10
 AVISIT = [REDACTED]

Tests for Location: Mu0=0

Test	-Statistic-	-----p Value-----
Student's t	t 0.121455	Pr > t 0.9034
Sign	M -0.5	Pr >= M 1.0000
Signed Rank	S 291	Pr >= S 0.7697

Quantiles (Definition 5)

Level	Quantile
100% Max	25.824025
99%	22.779706
95%	17.026880
90%	14.368205
75% Q3	7.330122
50% Median	-0.060104
25% Q1	-7.065623
10%	-13.686490
5%	-18.354843
1%	-24.242300
0% Min	-33.004507

SOURCE: MMRMDX1; TABLE: statlk.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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3 OF 9

STAT-4.9
Residual [REDACTED] from Proc Mixed for Change from Baseline in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

The UNIVARIATE Procedure
Variable: RESID (Residual)
AVISITN = 10
AVISIT = [REDACTED]

Extreme Observations

-----Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
-33.0045	93	20.3750	467
-24.5363	716	21.9446	97
-24.2423	34	22.7797	322
-24.1066	192	22.8236	301
-23.2337	440	25.8240	949

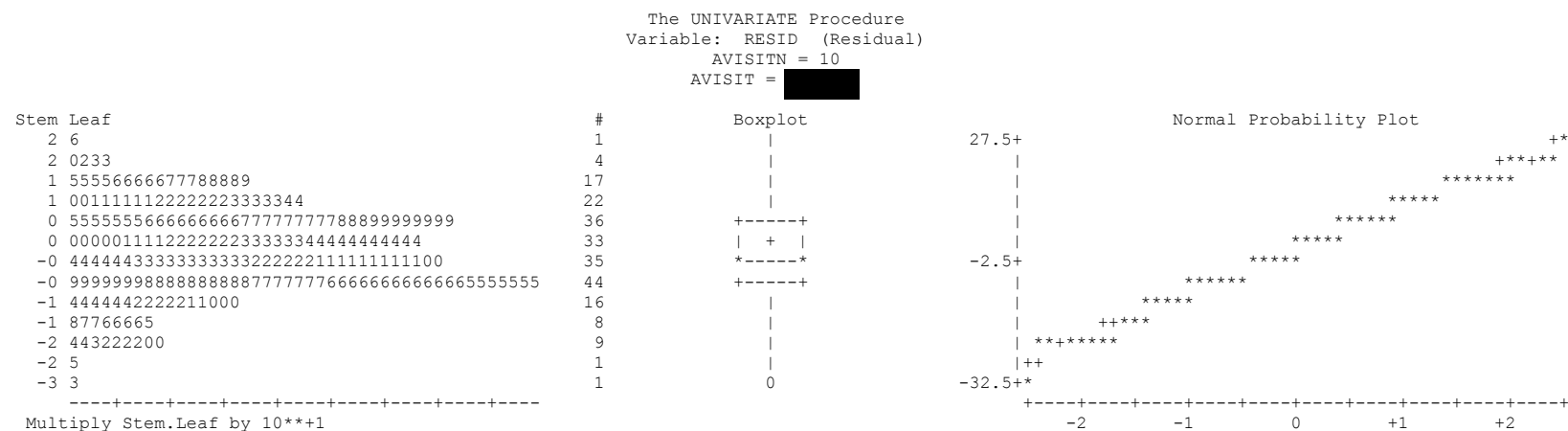
SOURCE: MMRMDX1; TABLE: statlk.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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 PROTOCOL 331-201-00061

4 OF 9

STAT-4.9
 Residual [REDACTED] from Proc Mixed for Change from Baseline in CAPS-5 Total Score, Primary Efficacy Analysis Model
 (Intent to Treat Sample)



SOURCE: MMRMDX1; TABLE: statlk.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.9 FINAL

BREXPIRAZOLE
PROTOCOL 331-201-00061

5 OF 9

Residual [REDACTED] from Proc Mixed for Change from Baseline in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)
AVISITN = 10
AVISIT = [REDACTED]

Moments

N	227	Sum Weights	227
Mean	0.00806674	Sum Observations	1.831149
Std Deviation	0.97676522	Variance	0.95407029
Skewness	-0.1794597	Kurtosis	-0.1289175
Uncorrected SS	215.634657	Corrected SS	215.619886
Coeff Variation	12108.5562	Std Error Mean	0.06483018

Basic Statistical Measures

Location		Variability	
Mean	0.00807	Std Deviation	0.97677
Median	-0.00547	Variance	0.95407
Mode	-0.50932	Range	5.40570
		Interquartile Range	1.31622

Note: The mode displayed is the smallest of 2 modes with a count of 2.

SOURCE: MMRMDX1; TABLE: statlk.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.9 FINAL

BREXPIRAZOLE
PROTOCOL 331-201-00061

6 OF 9

STAT-4.9
Residual [REDACTED] from Proc Mixed for Change from Baseline in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)
AVISITN = 10
AVISIT = [REDACTED]

Tests for Location: Mu0=0

Test	-Statistic-	-----p Value-----
Student's t	t 0.124429	Pr > t 0.9011
Sign	M -0.5	Pr >= M 1.0000
Signed Rank	S 290	Pr >= S 0.7704

Quantiles (Definition 5)

Level	Quantile
100% Max	2.35327141
99%	2.11123783
95%	1.55962015
90%	1.31465170
75% Q3	0.67188649
50% Median	-0.00547028
25% Q1	-0.64433297
10%	-1.24754229
5%	-1.67961704
1%	-2.20347197
0% Min	-3.05242422

SOURCE: MMRMDX1; TABLE: statlk.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.9 FINAL

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STAT-4.9
Residual [REDACTED] from Proc Mixed for Change from Baseline in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)
AVISITN = 10
AVISIT = [REDACTED]

Extreme Observations

-----Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
-3.05242	93	1.86278	467
-2.23710	716	2.02821	97
-2.20347	34	2.11124	301
-2.19831	192	2.11717	322
-2.11381	440	2.35327	949

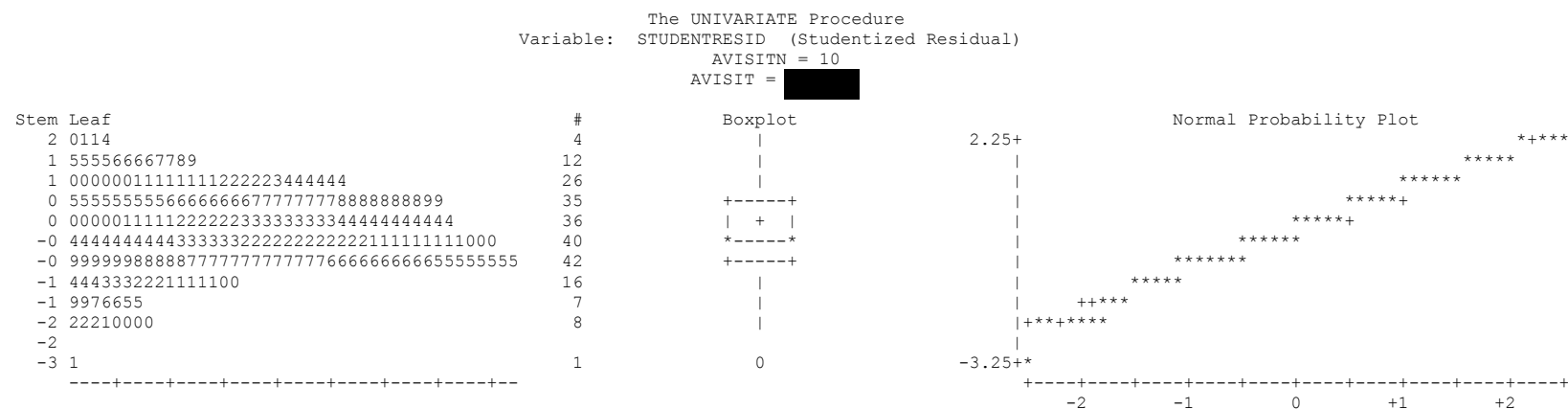
SOURCE: MMRMDX1; TABLE: statlk.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.9
Residual [REDACTED] from Proc Mixed for Change from Baseline in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)



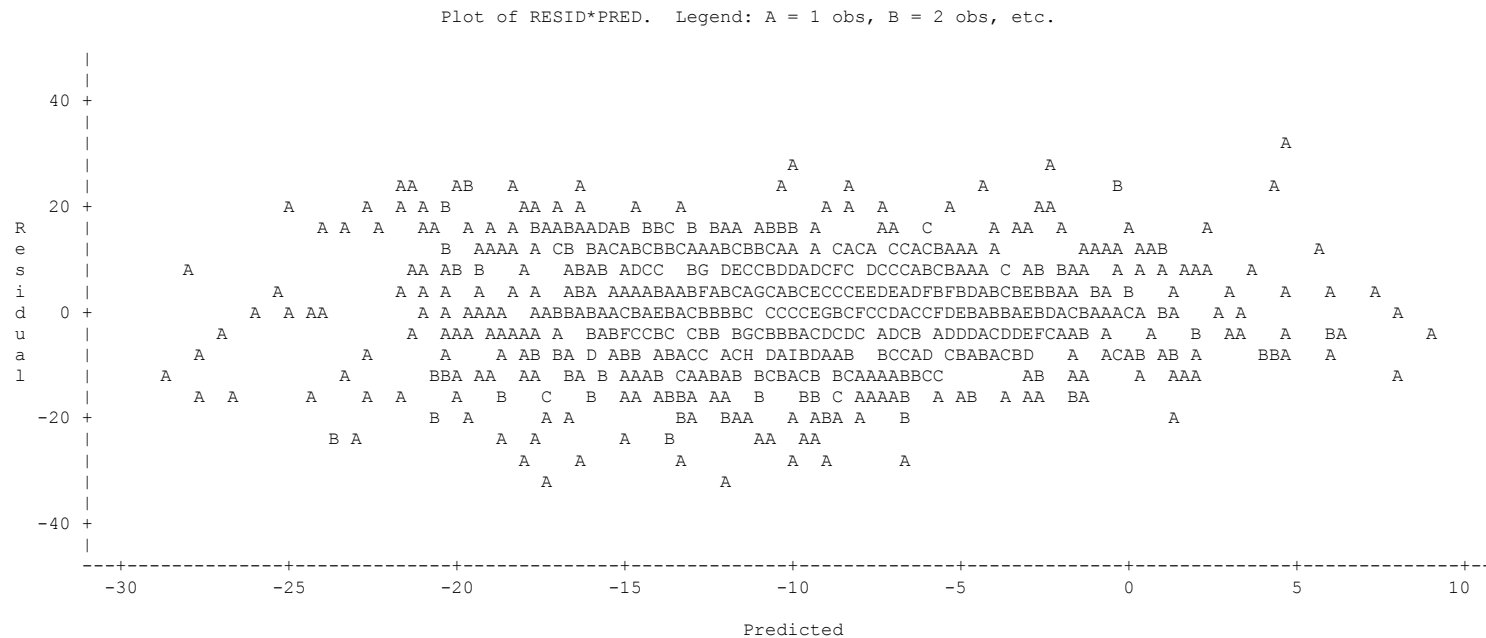
SOURCE: MMRMDX1; TABLE: statlk.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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9 OF 9

STAT-4.9
 Residual [REDACTED] from Proc Mixed for Change from Baseline in CAPS-5 Total Score, Primary Efficacy Analysis Model
 (Intent to Treat Sample)



SOURCE: MMRMDX1; TABLE: statlk.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIRAZOLE
PROTOCOL 331-201-00061

1 OF 20

STAT-4.10
Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Group Effect	TRTPN
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
AVISITN	4	3 6 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	
COMBFL	2	N Y

SOURCE: MMRMDX2; TABLE: stat11.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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PROTOCOL 331-201-00061

2 OF 20

STAT-4.10
Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	299	



SOURCE: MMRMDX2; TABLE: stat11.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.10 FINAL

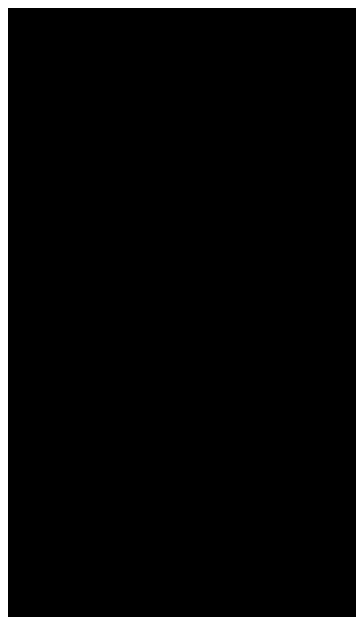
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STAT-4.10
Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----
The Mixed Procedure



SOURCE: MMRMDX2; TABLE: stat11.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-4.10 FINAL

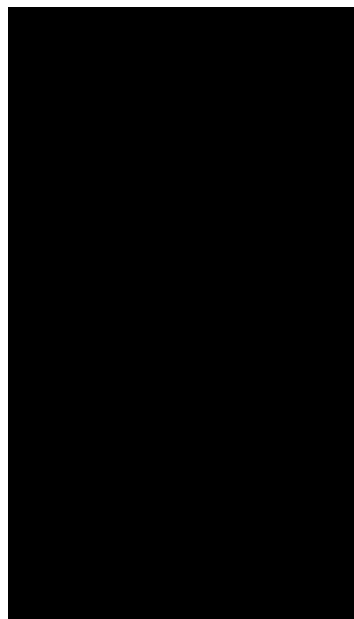
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PROTOCOL 331-201-00061

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STAT-4.10
Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



SOURCE: MMRMDX2; TABLE: stat11.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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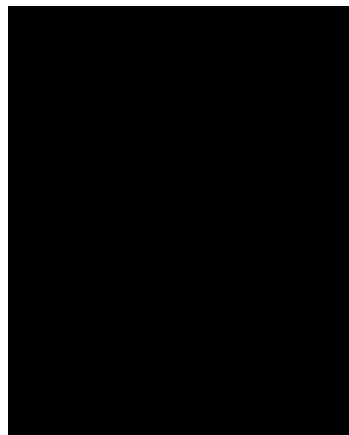
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PROTOCOL 331-201-00061

5 OF 20

STAT-4.10
Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
(Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure



Dimensions

Covariance Parameters	40
Columns in X	41
Columns in Z	0
Subjects	299

SOURCE: MMRMDX2; TABLE: stat11.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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 PROTOCOL 331-201-00061

6 OF 20

STAT-4.10
 Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
 (Intent to Treat Sample)

 ----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Dimensions

Max Obs per Subject 4

Number of Observations

Number of Observations Read	996
Number of Observations Used	996
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	7419.63261777	
1	2	6917.10751714	0.00489019
2	3	6909.33113519	0.00080739
3	1	6907.06145589	0.00002848
4	1	6906.98597457	0.00000009
5	1	6906.98574059	0.00000000

Convergence criteria met.

SOURCE: MMRMDX2; TABLE: stat11.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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7 OF 20

STAT-4.10
Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
(Intent to Treat Sample)

Parameter Code=CAPSTOT -----

The Mixed Procedure

Estimated R Matrix for SUBJID 001S00001

Row	Col1	Col2	Col3	Col4
1	95.2938	64.2572	64.5504	60.3472
2	64.2572	129.09	94.7811	91.9205
3	64.5504	94.7811	146.52	112.90
4	60.3472	91.9205	112.90	129.82

Estimated R Correlation Matrix for SUBJID 001S00001

Row	Col1	Col2	Col3	Col4
1	1.0000	0.5794	0.5463	0.5426
2	0.5794	1.0000	0.6892	0.7101
3	0.5463	0.6892	1.0000	0.8186
4	0.5426	0.7101	0.8186	1.0000

Estimated R Matrix for SUBJID 001S00011

Row	Col1	Col2	Col3	Col4
1	63.9185	43.6854	31.3695	37.4615
2	43.6854	98.9262	82.6187	72.2502
3	31.3695	82.6187	112.58	83.3850
4	37.4615	72.2502	83.3850	135.46

SOURCE: MMRMDX2; TABLE: stat11.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.10
 Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Estimated R Matrix for SUBJID 001S00101

Row	Col1	Col2	Col3	Col4
1	84.9865	58.8491	45.3790	54.8618
2	58.8491	114.92	95.4457	98.6286
3	45.3790	95.4457	134.77	130.88
4	54.8618	98.6286	130.88	173.25

Covariance Parameter Estimates

Cov Parm	Subject	Group	Estimate
UN(1,1)	SUBJID	TRTPN 1	95.2938
UN(2,1)	SUBJID	TRTPN 1	64.2572
UN(2,2)	SUBJID	TRTPN 1	129.09
UN(3,1)	SUBJID	TRTPN 1	64.5504
UN(3,2)	SUBJID	TRTPN 1	94.7811
UN(3,3)	SUBJID	TRTPN 1	146.52
UN(4,1)	SUBJID	TRTPN 1	60.3472
UN(4,2)	SUBJID	TRTPN 1	91.9205
UN(4,3)	SUBJID	TRTPN 1	112.90
UN(4,4)	SUBJID	TRTPN 1	129.82
UN(1,1)	SUBJID	TRTPN 2	66.1243
UN(2,1)	SUBJID	TRTPN 2	42.7734
UN(2,2)	SUBJID	TRTPN 2	111.53
UN(3,1)	SUBJID	TRTPN 2	34.2983

SOURCE: MMRMDX2; TABLE: stat11.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-4.10
 Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Group	Estimate
UN(3,2)	SUBJID	TRTPN 2	87.0247
UN(3,3)	SUBJID	TRTPN 2	102.29
UN(4,1)	SUBJID	TRTPN 2	37.8799
UN(4,2)	SUBJID	TRTPN 2	100.12
UN(4,3)	SUBJID	TRTPN 2	92.7002
UN(4,4)	SUBJID	TRTPN 2	149.81
UN(1,1)	SUBJID	TRTPN 3	63.9185
UN(2,1)	SUBJID	TRTPN 3	43.6854
UN(2,2)	SUBJID	TRTPN 3	98.9262
UN(3,1)	SUBJID	TRTPN 3	31.3695
UN(3,2)	SUBJID	TRTPN 3	82.6187
UN(3,3)	SUBJID	TRTPN 3	112.58
UN(4,1)	SUBJID	TRTPN 3	37.4615
UN(4,2)	SUBJID	TRTPN 3	72.2502
UN(4,3)	SUBJID	TRTPN 3	83.3850
UN(4,4)	SUBJID	TRTPN 3	135.46
UN(1,1)	SUBJID	TRTPN 900	84.9865
UN(2,1)	SUBJID	TRTPN 900	58.8491
UN(2,2)	SUBJID	TRTPN 900	114.92
UN(3,1)	SUBJID	TRTPN 900	45.3790
UN(3,2)	SUBJID	TRTPN 900	95.4457
UN(3,3)	SUBJID	TRTPN 900	134.77
UN(4,1)	SUBJID	TRTPN 900	54.8618
UN(4,2)	SUBJID	TRTPN 900	98.6286

SOURCE: MMRMDX2; TABLE: stat11.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-4.10
 Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
 (Intent to Treat Sample)

 ----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Group	Estimate
UN(4,3)	SUBJID	TRTPN 900	130.88
UN(4,4)	SUBJID	TRTPN 900	173.25

Fit Statistics

-2 Res Log Likelihood	6907.0
AIC (Smaller is Better)	6987.0
AICC (Smaller is Better)	6990.5
BIC (Smaller is Better)	7135.0

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
39	512.65	<.0001

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STAT-4.10
 Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Solution for Fixed Effects

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t
Intercept					3.4163	3.5355	296	0.97	0.3347
AVISITN			3		0.8999	2.7008	214	0.33	0.7393
AVISITN			6		0.3093	2.1603	181	0.14	0.8863
AVISITN			10		1.0883	1.8411	171	0.59	0.5552
AVISITN			12		0				
TRTPN				1	-5.7924	2.1332	135	-2.72	0.0075
TRTPN				2	-0.5506	2.2925	116	-0.24	0.8106
TRTPN				3	-3.4533	2.1810	125	-1.58	0.1159
TRTPN				900	0				
AVISITN*TRTPN			3	1	5.6229	1.9850	135	2.83	0.0053
AVISITN*TRTPN			3	2	2.1940	2.1980	122	1.00	0.3202
AVISITN*TRTPN			3	3	3.4684	2.0726	131	1.67	0.0966
AVISITN*TRTPN			3	900	0				
AVISITN*TRTPN			6	1	2.0607	1.6734	120	1.23	0.2206
AVISITN*TRTPN			6	2	1.4332	1.6822	108	0.85	0.3961
AVISITN*TRTPN			6	3	2.6949	1.7486	119	1.54	0.1259
AVISITN*TRTPN			6	900	0				
AVISITN*TRTPN			10	1	-0.4073	1.3134	110	-0.31	0.7571
AVISITN*TRTPN			10	2	-1.2545	1.5096	90.4	-0.83	0.4081
AVISITN*TRTPN			10	3	2.5005	1.5014	107	1.67	0.0988
AVISITN*TRTPN			10	900	0				

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STAT-4.10
 Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Solution for Fixed Effects

Effect	Center (Pooled Center) for ITT	Combat Related Population Flag	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t
AVISITN*TRTPN			12	1	0				
AVISITN*TRTPN			12	2	0				
AVISITN*TRTPN			12	3	0				
AVISITN*TRTPN			12	900	0				
POOLCNTR					-0.5650	3.1142	267	-0.18	0.8562
POOLCNTR					-1.1271	3.0551	268	-0.37	0.7125
POOLCNTR					-0.8652	2.5522	262	-0.34	0.7349
POOLCNTR					-0.3817	2.2754	263	-0.17	0.8669
POOLCNTR					-2.3250	2.4105	268	-0.96	0.3357
POOLCNTR					-4.6732	2.4453	261	-1.91	0.0571
POOLCNTR					-2.7844	2.4677	270	-1.13	0.2602
POOLCNTR					-5.1732	2.4762	255	-2.09	0.0377
POOLCNTR					-4.2543	2.5459	265	-1.67	0.0959
POOLCNTR					0				
COMBFL		N			3.0906	1.2799	275	2.41	0.0164
COMBFL		Y			0				
BASE*AVISITN			3		-0.2846	0.04867	254	-5.85	<.0001
BASE*AVISITN			6		-0.3432	0.06042	254	-5.68	<.0001
BASE*AVISITN			10		-0.4074	0.06369	212	-6.40	<.0001
BASE*AVISITN			12		-0.4083	0.06909	222	-5.91	<.0001

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STAT-4.10
 Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
AVISITN	3	212	0.80	0.4943
TRTPN	3	146	2.72	0.0466
AVISITN*TRTPN	9	165	1.86	0.0618
POOLCNTR	9	268	1.46	0.1646
COMBFL	1	275	5.83	0.0164
BASE*AVISITN	4	216	13.09	<.0001

Least Squares Means

Effect	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN	3	1	-6.6009	1.1949	83.3	-5.52	<.0001	0.05	-8.9774	-4.2244
AVISITN*TRTPN	3	2	-4.7879	1.1054	80.3	-4.33	<.0001	0.05	-6.9876	-2.5882
AVISITN*TRTPN	3	3	-6.4163	1.0232	86.8	-6.27	<.0001	0.05	-8.4502	-4.3824
AVISITN*TRTPN	3	900	-6.4314	1.1239	88.9	-5.72	<.0001	0.05	-8.6645	-4.1982
AVISITN*TRTPN	6	1	-12.8284	1.4258	74.9	-9.00	<.0001	0.05	-15.6687	-9.9880
AVISITN*TRTPN	6	2	-8.2140	1.4342	78.1	-5.73	<.0001	0.05	-11.0693	-5.3587
AVISITN*TRTPN	6	3	-9.8551	1.2959	77	-7.60	<.0001	0.05	-12.4356	-7.2745
AVISITN*TRTPN	6	900	-9.0966	1.3151	80.5	-6.92	<.0001	0.05	-11.7135	-6.4797
AVISITN*TRTPN	10	1	-16.7911	1.5460	72.5	-10.86	<.0001	0.05	-19.8726	-13.7096

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STAT-4.10
 Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----												
The Mixed Procedure												
Least Squares Means												
Effect	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper		
AVISITN*TRTPN	10	2	-12.3965	1.4409	65.1	-8.60	<.0001	0.05	-15.2741	-9.5190		
AVISITN*TRTPN	10	3	-11.5443	1.4063	62.7	-8.21	<.0001	0.05	-14.3549	-8.7336		
AVISITN*TRTPN	10	900	-10.5914	1.4489	78.2	-7.31	<.0001	0.05	-13.4759	-7.7070		
AVISITN*TRTPN	12	1	-17.5059	1.4677	75.9	-11.93	<.0001	0.05	-20.4291	-14.5827		
AVISITN*TRTPN	12	2	-12.2640	1.7206	60.9	-7.13	<.0001	0.05	-15.7046	-8.8234		
AVISITN*TRTPN	12	3	-15.1667	1.5466	63.6	-9.81	<.0001	0.05	-18.2567	-12.0767		
AVISITN*TRTPN	12	900	-11.7134	1.6421	75.8	-7.13	<.0001	0.05	-14.9841	-8.4428		
Differences of Least Squares Means												
Effect	Analysis Visit (N)	Planned Treatment (N)	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN	3	1	3	2	-1.8130	1.5140	138	-1.20	0.2332	0.05	-4.8067	1.1807
AVISITN*TRTPN	3	1	3	3	-0.1846	1.4694	134	-0.13	0.9002	0.05	-3.0909	2.7217
AVISITN*TRTPN	3	1	3	900	-0.1696	1.5427	145	-0.11	0.9126	0.05	-3.2187	2.8796
AVISITN*TRTPN	3	1	6	1	6.2275	1.2231	66.9	5.09	<.0001	0.05	3.7862	8.6687
AVISITN*TRTPN	3	1	6	2	1.6131	1.7620	127	0.92	0.3617	0.05	-1.8737	5.0998
AVISITN*TRTPN	3	1	6	3	3.2541	1.6698	134	1.95	0.0534	0.05	-0.04844	6.5567
AVISITN*TRTPN	3	1	6	900	2.4957	1.6874	138	1.48	0.1414	0.05	-0.8408	5.8322

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STAT-4.10
 Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Differences of Least Squares Means

Effect	Analysis Visit (N)	Planned Treatment (N)	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN	3	1	10	1	10.1902	1.3566	66.6	7.51	<.0001	0.05	7.4821	12.8983
AVISITN*TRTPN	3	1	10	2	5.7956	1.7651	112	3.28	0.0014	0.05	2.2984	9.2929
AVISITN*TRTPN	3	1	10	3	4.9434	1.7573	117	2.81	0.0058	0.05	1.4630	8.4237
AVISITN*TRTPN	3	1	10	900	3.9905	1.7942	133	2.22	0.0278	0.05	0.4417	7.5393
AVISITN*TRTPN	3	1	12	1	10.9049	1.3091	67.5	8.33	<.0001	0.05	8.2923	13.5176
AVISITN*TRTPN	3	1	12	2	5.6631	2.0010	98.4	2.83	0.0056	0.05	1.6924	9.6337
AVISITN*TRTPN	3	1	12	3	8.5658	1.8712	114	4.58	<.0001	0.05	4.8588	12.2728
AVISITN*TRTPN	3	1	12	900	5.1125	1.9530	125	2.62	0.0099	0.05	1.2472	8.9778
AVISITN*TRTPN	3	2	3	3	1.6284	1.3777	129	1.18	0.2394	0.05	-1.0974	4.3541
AVISITN*TRTPN	3	2	3	900	1.6434	1.4525	134	1.13	0.2599	0.05	-1.2295	4.5163
AVISITN*TRTPN	3	2	6	1	8.0404	1.7049	124	4.72	<.0001	0.05	4.6659	11.4150
AVISITN*TRTPN	3	2	6	2	3.4260	1.2536	60.5	2.73	0.0082	0.05	0.9188	5.9333
AVISITN*TRTPN	3	2	6	3	5.0671	1.5887	127	3.19	0.0018	0.05	1.9232	8.2110
AVISITN*TRTPN	3	2	6	900	4.3087	1.6063	128	2.68	0.0083	0.05	1.1303	7.4871
AVISITN*TRTPN	3	2	10	1	12.0032	1.8070	117	6.64	<.0001	0.05	8.4247	15.5817
AVISITN*TRTPN	3	2	10	2	7.6086	1.3510	55.3	5.63	<.0001	0.05	4.9015	10.3158
AVISITN*TRTPN	3	2	10	3	6.7564	1.6802	105	4.02	0.0001	0.05	3.4250	10.0877
AVISITN*TRTPN	3	2	10	900	5.8035	1.7189	125	3.38	0.0010	0.05	2.4017	9.2053
AVISITN*TRTPN	3	2	12	1	12.7179	1.7404	124	7.31	<.0001	0.05	9.2731	16.1628
AVISITN*TRTPN	3	2	12	2	7.4761	1.6156	56.9	4.63	<.0001	0.05	4.2407	10.7114
AVISITN*TRTPN	3	2	12	3	10.3788	1.7993	99.3	5.77	<.0001	0.05	6.8087	13.9489
AVISITN*TRTPN	3	2	12	900	6.9255	1.8837	114	3.68	0.0004	0.05	3.1938	10.6572

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STAT-4.10
 Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Differences of Least Squares Means

Effect	Analysis Visit (N)	Planned Treatment (N)	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN	3	3	3	900	0.01508	1.4057	147	0.01	0.9915	0.05	-2.7629	2.7930
AVISITN*TRTPN	3	3	6	1	6.4121	1.6647	121	3.85	0.0002	0.05	3.1163	9.7078
AVISITN*TRTPN	3	3	6	2	1.7977	1.6434	113	1.09	0.2763	0.05	-1.4582	5.0536
AVISITN*TRTPN	3	3	6	3	3.4388	1.0907	64.2	3.15	0.0025	0.05	1.2601	5.6175
AVISITN*TRTPN	3	3	6	900	2.6803	1.5634	131	1.71	0.0888	0.05	-0.4124	5.7731
AVISITN*TRTPN	3	3	10	1	10.3748	1.7686	113	5.87	<.0001	0.05	6.8711	13.8786
AVISITN*TRTPN	3	3	10	2	5.9803	1.6456	97.4	3.63	0.0004	0.05	2.7143	9.2462
AVISITN*TRTPN	3	3	10	3	5.1280	1.3490	63.4	3.80	0.0003	0.05	2.4326	7.8234
AVISITN*TRTPN	3	3	10	900	4.1751	1.6784	122	2.49	0.0142	0.05	0.8526	7.4977
AVISITN*TRTPN	3	3	12	1	11.0896	1.7002	120	6.52	<.0001	0.05	7.7233	14.4559
AVISITN*TRTPN	3	3	12	2	5.8477	1.8972	84.6	3.08	0.0028	0.05	2.0753	9.6201
AVISITN*TRTPN	3	3	12	3	8.7505	1.4373	61.3	6.09	<.0001	0.05	5.8767	11.6242
AVISITN*TRTPN	3	3	12	900	5.2971	1.8466	112	2.87	0.0049	0.05	1.6384	8.9559
AVISITN*TRTPN	3	900	6	1	6.3970	1.7300	128	3.70	0.0003	0.05	2.9740	9.8201
AVISITN*TRTPN	3	900	6	2	1.7826	1.7093	124	1.04	0.2990	0.05	-1.6007	5.1659
AVISITN*TRTPN	3	900	6	3	3.4237	1.6140	131	2.12	0.0358	0.05	0.2307	6.6167
AVISITN*TRTPN	3	900	6	900	2.6653	1.0768	70.6	2.48	0.0157	0.05	0.5180	4.8125
AVISITN*TRTPN	3	900	10	1	10.3598	1.8306	120	5.66	<.0001	0.05	6.7354	13.9841
AVISITN*TRTPN	3	900	10	2	5.9652	1.7124	105	3.48	0.0007	0.05	2.5700	9.3604
AVISITN*TRTPN	3	900	10	3	5.1129	1.7042	110	3.00	0.0033	0.05	1.7356	8.4903
AVISITN*TRTPN	3	900	10	900	4.1601	1.3699	72.8	3.04	0.0033	0.05	1.4297	6.8904
AVISITN*TRTPN	3	900	12	1	11.0745	1.7648	127	6.28	<.0001	0.05	7.5823	14.5667

SOURCE: MMRMDX2; TABLE: stat11.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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STAT-4.10
 Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Differences of Least Squares Means

Effect	Analysis Visit (N)	Planned Treatment (N)	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN	3	900	12	2	5.8326	1.9548	91.2	2.98	0.0037	0.05	1.9497	9.7155
AVISITN*TRTPN	3	900	12	3	8.7354	1.8216	106	4.80	<.0001	0.05	5.1240	12.3467
AVISITN*TRTPN	3	900	12	900	5.2821	1.4917	69.6	3.54	0.0007	0.05	2.3066	8.2575
AVISITN*TRTPN	6	1	6	2	-4.6144	1.9292	130	-2.39	0.0182	0.05	-8.4311	-0.7977
AVISITN*TRTPN	6	1	6	3	-2.9733	1.8437	130	-1.61	0.1092	0.05	-6.6207	0.6741
AVISITN*TRTPN	6	1	6	900	-3.7318	1.8604	135	-2.01	0.0469	0.05	-7.4111	-0.05240
AVISITN*TRTPN	6	1	10	1	3.9628	1.2220	58.7	3.24	0.0020	0.05	1.5172	6.4083
AVISITN*TRTPN	6	1	10	2	-0.4318	1.9321	119	-0.22	0.8235	0.05	-4.2574	3.3938
AVISITN*TRTPN	6	1	10	3	-1.2841	1.9233	121	-0.67	0.5056	0.05	-5.0919	2.5237
AVISITN*TRTPN	6	1	10	900	-2.2369	1.9577	138	-1.14	0.2552	0.05	-6.1079	1.6340
AVISITN*TRTPN	6	1	12	1	4.6775	1.1544	56.8	4.05	0.0002	0.05	2.3656	6.9894
AVISITN*TRTPN	6	1	12	2	-0.5644	2.1497	110	-0.26	0.7934	0.05	-4.8245	3.6957
AVISITN*TRTPN	6	1	12	3	2.3384	2.0280	123	1.15	0.2511	0.05	-1.6760	6.3527
AVISITN*TRTPN	6	1	12	900	-1.1149	2.1042	134	-0.53	0.5971	0.05	-5.2768	3.0469
AVISITN*TRTPN	6	2	6	3	1.6411	1.8268	126	0.90	0.3707	0.05	-1.9741	5.2562
AVISITN*TRTPN	6	2	6	900	0.8826	1.8406	131	0.48	0.6324	0.05	-2.7586	4.5238
AVISITN*TRTPN	6	2	10	1	8.5771	2.0201	129	4.25	<.0001	0.05	4.5802	12.5741
AVISITN*TRTPN	6	2	10	2	4.1826	0.9231	47	4.53	<.0001	0.05	2.3255	6.0396
AVISITN*TRTPN	6	2	10	3	3.3303	1.9069	117	1.75	0.0833	0.05	-0.4460	7.1066
AVISITN*TRTPN	6	2	10	900	2.3775	1.9401	132	1.23	0.2226	0.05	-1.4602	6.2151
AVISITN*TRTPN	6	2	12	1	9.2919	1.9608	131	4.74	<.0001	0.05	5.4130	13.1707
AVISITN*TRTPN	6	2	12	2	4.0500	1.1682	46.1	3.47	0.0012	0.05	1.6987	6.4014

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BREXPIRAZOLE
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STAT-4.10
 Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Differences of Least Squares Means

Effect	Analysis Visit (N)	Planned Treatment (N)	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN	6	2	12	3	6.9528	2.0123	116	3.46	0.0008	0.05	2.9672	10.9384
AVISITN*TRTPN	6	2	12	900	3.4995	2.0874	129	1.68	0.0961	0.05	-0.6303	7.6292
AVISITN*TRTPN	6	3	6	900	-0.7584	1.7545	136	-0.43	0.6662	0.05	-4.2282	2.7113
AVISITN*TRTPN	6	3	10	1	6.9361	1.9378	127	3.58	0.0005	0.05	3.1014	10.7707
AVISITN*TRTPN	6	3	10	2	2.5415	1.8286	112	1.39	0.1673	0.05	-1.0816	6.1646
AVISITN*TRTPN	6	3	10	3	1.6892	0.9099	56.3	1.86	0.0686	0.05	-0.1333	3.5118
AVISITN*TRTPN	6	3	10	900	0.7364	1.8574	133	0.40	0.6924	0.05	-2.9374	4.4101
AVISITN*TRTPN	6	3	12	1	7.6508	1.8756	130	4.08	<.0001	0.05	3.9400	11.3616
AVISITN*TRTPN	6	3	12	2	2.4089	2.0579	100	1.17	0.2445	0.05	-1.6739	6.4918
AVISITN*TRTPN	6	3	12	3	5.3117	1.2605	56.3	4.21	<.0001	0.05	2.7869	7.8365
AVISITN*TRTPN	6	3	12	900	1.8584	2.0107	128	0.92	0.3571	0.05	-2.1201	5.8368
AVISITN*TRTPN	6	900	10	1	7.6945	1.9543	130	3.94	0.0001	0.05	3.8280	11.5610
AVISITN*TRTPN	6	900	10	2	3.2999	1.8437	116	1.79	0.0761	0.05	-0.3519	6.9518
AVISITN*TRTPN	6	900	10	3	2.4477	1.8377	121	1.33	0.1854	0.05	-1.1905	6.0858
AVISITN*TRTPN	6	900	10	900	1.4948	0.9690	64.7	1.54	0.1278	0.05	-0.4406	3.4302
AVISITN*TRTPN	6	900	12	1	8.4092	1.8929	136	4.44	<.0001	0.05	4.6658	12.1526
AVISITN*TRTPN	6	900	12	2	3.1674	2.0707	103	1.53	0.1292	0.05	-0.9393	7.2740
AVISITN*TRTPN	6	900	12	3	6.0701	1.9469	119	3.12	0.0023	0.05	2.2151	9.9251
AVISITN*TRTPN	6	900	12	900	2.6168	1.2111	63.6	2.16	0.0345	0.05	0.1972	5.0365
AVISITN*TRTPN	10	1	10	2	-4.3946	2.0231	120	-2.17	0.0318	0.05	-8.4002	-0.3890
AVISITN*TRTPN	10	1	10	3	-5.2468	2.0131	122	-2.61	0.0103	0.05	-9.2319	-1.2618
AVISITN*TRTPN	10	1	10	900	-6.1997	2.0474	132	-3.03	0.0030	0.05	-10.2495	-2.1499

SOURCE: MMRMDX2; TABLE: stat11.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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 PROTOCOL 331-201-00061

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STAT-4.10
 Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Differences of Least Squares Means

Effect	Analysis Visit (N)	Planned Treatment (N)	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN	10	1	12	1	0.7147	0.9557	53.1	0.75	0.4578	0.05	-1.2021	2.6316
AVISITN*TRTPN	10	1	12	2	-4.5271	2.2318	114	-2.03	0.0448	0.05	-8.9484	-0.1059
AVISITN*TRTPN	10	1	12	3	-1.6244	2.1136	124	-0.77	0.4436	0.05	-5.8077	2.5590
AVISITN*TRTPN	10	1	12	900	-5.0777	2.1878	133	-2.32	0.0218	0.05	-9.4051	-0.7503
AVISITN*TRTPN	10	2	10	3	-0.8523	1.9095	104	-0.45	0.6563	0.05	-4.6386	2.9341
AVISITN*TRTPN	10	2	10	900	-1.8051	1.9428	119	-0.93	0.3547	0.05	-5.6521	2.0419
AVISITN*TRTPN	10	2	12	1	5.1093	1.9638	120	2.60	0.0104	0.05	1.2213	8.9974
AVISITN*TRTPN	10	2	12	2	-0.1325	1.2117	46.4	-0.11	0.9134	0.05	-2.5710	2.3059
AVISITN*TRTPN	10	2	12	3	2.7702	2.0144	107	1.38	0.1720	0.05	-1.2232	6.7636
AVISITN*TRTPN	10	2	12	900	-0.6831	2.0899	119	-0.33	0.7443	0.05	-4.8213	3.4550
AVISITN*TRTPN	10	3	10	900	-0.9528	1.9367	124	-0.49	0.6236	0.05	-4.7862	2.8805
AVISITN*TRTPN	10	3	12	1	5.9616	1.9535	121	3.05	0.0028	0.05	2.0942	9.8290
AVISITN*TRTPN	10	3	12	2	0.7197	2.1298	101	0.34	0.7361	0.05	-3.5052	4.9446
AVISITN*TRTPN	10	3	12	3	3.6225	1.2008	57.5	3.02	0.0038	0.05	1.2182	6.0267
AVISITN*TRTPN	10	3	12	900	0.1691	2.0841	124	0.08	0.9354	0.05	-3.9559	4.2942
AVISITN*TRTPN	10	900	12	1	6.9144	1.9887	137	3.48	0.0007	0.05	2.9818	10.8471
AVISITN*TRTPN	10	900	12	2	1.6726	2.1595	110	0.77	0.4403	0.05	-2.6070	5.9521
AVISITN*TRTPN	10	900	12	3	4.5753	2.0405	123	2.24	0.0267	0.05	0.5364	8.6142
AVISITN*TRTPN	10	900	12	900	1.1220	0.9007	58.8	1.25	0.2178	0.05	-0.6804	2.9244
AVISITN*TRTPN	12	1	12	2	-5.2419	2.1786	112	-2.41	0.0178	0.05	-9.5587	-0.9251
AVISITN*TRTPN	12	1	12	3	-2.3391	2.0564	123	-1.14	0.2575	0.05	-6.4097	1.7314
AVISITN*TRTPN	12	1	12	900	-5.7924	2.1332	135	-2.72	0.0075	0.05	-10.0113	-1.5735

SOURCE: MMRMDX2; TABLE: stat11.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-4.10
 Proc Mixed Output Using Heterogeneous Variance Structure for Treatment Groups
 (Intent to Treat Sample)

----- Parameter Code=CAPSTOT -----

The Mixed Procedure

Differences of Least Squares Means

Effect	Analysis Visit (N)	Planned Treatment (N)	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN	12	2	12	3	2.9027	2.2253	104	1.30	0.1950	0.05	-1.5100	7.3155
AVISITN*TRTPN	12	2	12	900	-0.5506	2.2925	116	-0.24	0.8106	0.05	-5.0912	3.9901
AVISITN*TRTPN	12	3	12	900	-3.4533	2.1810	125	-1.58	0.1159	0.05	-7.7697	0.8631

Tests of Effect Slices

Effect	Analysis Visit (N)	Num DF	Den DF	F Value	Pr > F
AVISITN*TRTPN	3	3	152	0.69	0.5588
AVISITN*TRTPN	6	3	145	2.14	0.0973
AVISITN*TRTPN	10	3	131	3.47	0.0181
AVISITN*TRTPN	12	3	131	3.15	0.0271

SOURCE: MMRMDX2; TABLE: stat11.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-5.1
Proc Mixed Output for Change [REDACTED] in CGI-S Scale, MMRM (UN)
(Intent to Treat Sample)

Parameter Code=CGI0101 -----

The Mixed Procedure

Model Information

Data Set	WORK.INDATA
Dependent Variable	CHG
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
AVISITN	7	2 3 4 6 8 10 12
TRTPN	4	1 2 3 900
POOLCNTR	10	[REDACTED]
COMBFL	2	N Y

SOURCE: MMRMOUT; TABLE: statlcgisa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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STAT-5.1
Proc Mixed Output for Change ██████████ in CGI-S Scale, MMRM (UN)
(Intent to Treat Sample)

----- Parameter Code=CGI0101 -----

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	307	

SOURCE: MMRMOUT; TABLE: statlcgisa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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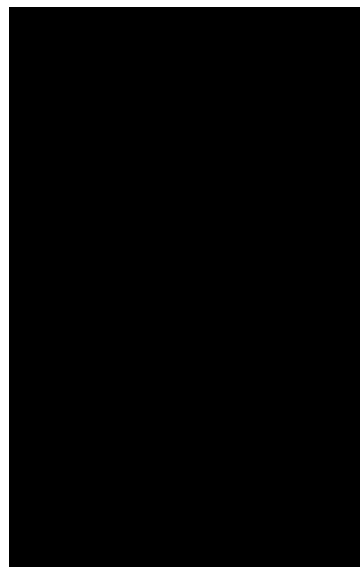
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STAT-5.1
Proc Mixed Output for Change [REDACTED] in CGI-S Scale, MMRM (UN)
(Intent to Treat Sample)

----- Parameter Code=CGI0101 -----

The Mixed Procedure



SOURCE: MMRMOUT; TABLE: statlcgisa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
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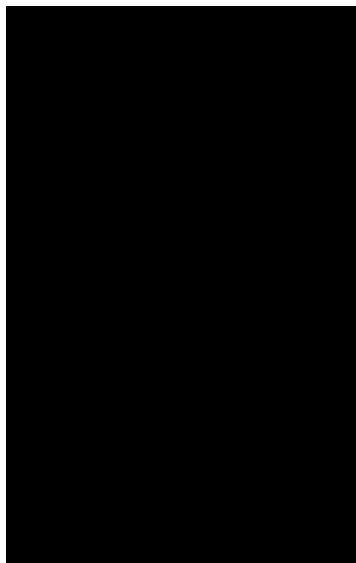
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STAT-5.1
Proc Mixed Output for Change ██████████ in CGI-S Scale, MMRM (UN)
(Intent to Treat Sample)

----- Parameter Code=CGI0101 -----

The Mixed Procedure



SOURCE: MMRMOUT; TABLE: statlcgisa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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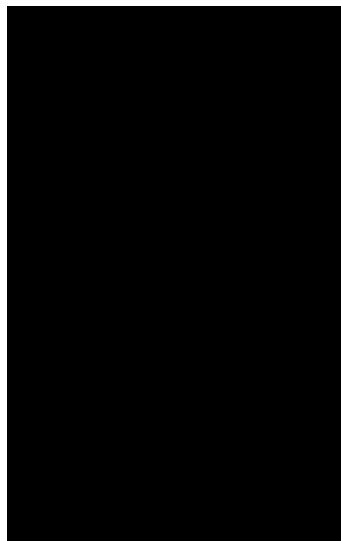
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STAT-5.1
Proc Mixed Output for Change [REDACTED] in CGI-S Scale, MMRM (UN)
(Intent to Treat Sample)

----- Parameter Code=CGI0101 -----

The Mixed Procedure



SOURCE: MMRMOUT; TABLE: statlcgisa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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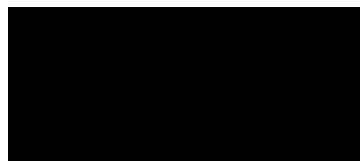
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STAT-5.1
Proc Mixed Output for Change ██████████ in CGI-S Scale, MMRM (UN)
(Intent to Treat Sample)

----- Parameter Code=CGI0101 -----

The Mixed Procedure



Dimensions

Covariance Parameters	28
Columns in X	59
Columns in Z	0
Subjects	307
Max Obs per Subject	7

Number of Observations

Number of Observations Read	1835
Number of Observations Used	1835
Number of Observations Not Used	0

SOURCE: MMRMOUT; TABLE: statlcgisa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-5.1
 Proc Mixed Output for Change ██████████ in CGI-S Scale, MMRM (UN)
 (Intent to Treat Sample)

----- Parameter Code=CGI0101 -----

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	4851.38437141	
1	2	3735.95790100	0.00203330
2	1	3735.47643679	0.00002165
3	1	3735.47157376	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	0.3388
UN(2,1)	SUBJID	0.1749
UN(2,2)	SUBJID	0.5893
UN(3,1)	SUBJID	0.2131
UN(3,2)	SUBJID	0.4334
UN(3,3)	SUBJID	0.8444
UN(4,1)	SUBJID	0.1604
UN(4,2)	SUBJID	0.4051

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 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-5.1 FINAL

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BREXPIRAZOLE
PROTOCOL 331-201-00061

8 OF 14

STAT-5.1
Proc Mixed Output for Change ██████████ in CGI-S Scale, MMRM (UN)
(Intent to Treat Sample)

----- Parameter Code=CGI0101 -----

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,3)	SUBJID	0.5940
UN(4,4)	SUBJID	0.9222
UN(5,1)	SUBJID	0.2120
UN(5,2)	SUBJID	0.4086
UN(5,3)	SUBJID	0.6034
UN(5,4)	SUBJID	0.7293
UN(5,5)	SUBJID	0.9313
UN(6,1)	SUBJID	0.1658
UN(6,2)	SUBJID	0.3241
UN(6,3)	SUBJID	0.5341
UN(6,4)	SUBJID	0.6845
UN(6,5)	SUBJID	0.6721
UN(6,6)	SUBJID	0.9841
UN(7,1)	SUBJID	0.1713
UN(7,2)	SUBJID	0.3593
UN(7,3)	SUBJID	0.5630
UN(7,4)	SUBJID	0.6681
UN(7,5)	SUBJID	0.6294
UN(7,6)	SUBJID	0.8219
UN(7,7)	SUBJID	1.1546

SOURCE: MMRMOUT; TABLE: statlcgisa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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9 OF 14

Proc Mixed Output for Change [REDACTED] STAT-5.1
 (Intent to Treat Sample) in CGI-S Scale, MMRM (UN)

----- Parameter Code=CGI0101 -----

The Mixed Procedure

Fit Statistics

-2 Res Log Likelihood	3735.5
AIC (Smaller is Better)	3791.5
AICC (Smaller is Better)	3792.4
BIC (Smaller is Better)	3895.8

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
27	1115.91	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
AVISITN	6	247	0.71	0.6401
TRTPN	3	290	2.52	0.0585
AVISITN*TRTPN	18	497	1.41	0.1204
POOLCNTR	9	293	1.95	0.0456
COMBFL	1	291	2.54	0.1120

SOURCE: MMRMOUT; TABLE: statlcgisa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIRAZOLE
 PROTOCOL 331-201-00061

10 OF 14

Proc Mixed Output for Change [REDACTED] in CGI-S Scale, MMRM (UN)
 (Intent to Treat Sample)

STAT-5.1

Parameter Code=CGI0101

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
BASE*AVISITN	7	256	10.55	<.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
WEEK2 1 vs 900	-0.1186	0.09390	287	-1.26	0.2077	0.05	-0.3034	0.06624
WEEK3 1 vs 900	-0.08376	0.1237	291	-0.68	0.4989	0.05	-0.3272	0.1597
WEEK4 1 vs 900	-0.1233	0.1491	286	-0.83	0.4092	0.05	-0.4168	0.1703
WEEK6 1 vs 900	-0.2702	0.1593	277	-1.70	0.0910	0.05	-0.5839	0.04345
WEEK8 1 vs 900	-0.4141	0.1607	277	-2.58	0.0105	0.05	-0.7304	-0.09771
WEEK10 1 vs 900	-0.4733	0.1694	263	-2.79	0.0056	0.05	-0.8070	-0.1397
WEEK12 1 vs 900	-0.4096	0.1870	255	-2.19	0.0294	0.05	-0.7778	-0.04144
WEEK2 1 vs 2	-0.1588	0.09687	287	-1.64	0.1023	0.05	-0.3494	0.03190
WEEK3 1 vs 2	-0.2260	0.1286	295	-1.76	0.0799	0.05	-0.4791	0.02711
WEEK4 1 vs 2	-0.2073	0.1543	287	-1.34	0.1801	0.05	-0.5110	0.09634
WEEK6 1 vs 2	-0.3450	0.1665	284	-2.07	0.0391	0.05	-0.6727	-0.01740
WEEK8 1 vs 2	-0.4495	0.1684	287	-2.67	0.0080	0.05	-0.7809	-0.1181

SOURCE: MMRMOUT; TABLE: statlcgisa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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Proc Mixed Output for Change [REDACTED] in CGI-S Scale, MMRM (UN)
 (Intent to Treat Sample)

Parameter Code=CGI0101

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
WEEK10 1 vs 2	-0.2599	0.1791	273	-1.45	0.1480	0.05	-0.6125	0.09274
WEEK12 1 vs 2	-0.3038	0.1977	261	-1.54	0.1257	0.05	-0.6932	0.08557
WEEK2 1 vs 3	-0.1143	0.09458	286	-1.21	0.2279	0.05	-0.3005	0.07187
WEEK3 1 vs 3	-0.09081	0.1254	293	-0.72	0.4695	0.05	-0.3376	0.1559
WEEK4 1 vs 3	-0.06095	0.1512	288	-0.40	0.6872	0.05	-0.3585	0.2366
WEEK6 1 vs 3	-0.2176	0.1631	283	-1.33	0.1832	0.05	-0.5385	0.1034
WEEK8 1 vs 3	-0.5563	0.1647	284	-3.38	0.0008	0.05	-0.8805	-0.2321
WEEK10 1 vs 3	-0.4159	0.1727	264	-2.41	0.0167	0.05	-0.7559	-0.07594
WEEK12 1 vs 3	-0.2245	0.1908	257	-1.18	0.2405	0.05	-0.6004	0.1513
WEEK2 2 vs 900	0.04019	0.09654	287	0.42	0.6775	0.05	-0.1498	0.2302
WEEK3 2 vs 900	0.1422	0.1275	292	1.12	0.2656	0.05	-0.1087	0.3932
WEEK4 2 vs 900	0.08409	0.1532	285	0.55	0.5834	0.05	-0.2174	0.3856
WEEK6 2 vs 900	0.07481	0.1637	277	0.46	0.6480	0.05	-0.2474	0.3970
WEEK8 2 vs 900	0.03542	0.1654	280	0.21	0.8306	0.05	-0.2901	0.3610
WEEK10 2 vs 900	-0.2135	0.1766	272	-1.21	0.2278	0.05	-0.5612	0.1342
WEEK12 2 vs 900	-0.1058	0.1946	260	-0.54	0.5869	0.05	-0.4889	0.2773
WEEK2 3 vs 900	-0.00429	0.09405	286	-0.05	0.9637	0.05	-0.1894	0.1808
WEEK3 3 vs 900	0.007051	0.1243	290	0.06	0.9548	0.05	-0.2376	0.2517
WEEK4 3 vs 900	-0.06230	0.1502	286	-0.41	0.6785	0.05	-0.3579	0.2333
WEEK6 3 vs 900	-0.05266	0.1606	278	-0.33	0.7432	0.05	-0.3688	0.2635

SOURCE: MMRMOUT; TABLE: statlcgisa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAF/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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Proc Mixed Output for Change [REDACTED] in CGI-S Scale, MMRM (UN)
 (Intent to Treat Sample)

Parameter Code=CGI0101

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
WEEK8 3 vs 900	0.1422	0.1618	278	0.88	0.3803	0.05	-0.1764	0.4608
WEEK10 3 vs 900	-0.05741	0.1706	264	-0.34	0.7368	0.05	-0.3934	0.2786
WEEK12 3 vs 900	-0.1851	0.1880	255	-0.98	0.3259	0.05	-0.5554	0.1852

Least Squares Means

Effect	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN	2	1	-0.3731	0.07074	296	-5.27	<.0001	0.05	-0.5123	-0.2339
AVISITN*TRTPN	2	2	-0.2144	0.07585	300	-2.83	0.0050	0.05	-0.3636	-0.06509
AVISITN*TRTPN	2	3	-0.2588	0.07162	296	-3.61	0.0004	0.05	-0.3998	-0.1179
AVISITN*TRTPN	2	900	-0.2546	0.07118	301	-3.58	0.0004	0.05	-0.3946	-0.1145
AVISITN*TRTPN	3	1	-0.5670	0.09140	314	-6.20	<.0001	0.05	-0.7468	-0.3871
AVISITN*TRTPN	3	2	-0.3410	0.09777	321	-3.49	0.0006	0.05	-0.5333	-0.1486
AVISITN*TRTPN	3	3	-0.4761	0.09266	314	-5.14	<.0001	0.05	-0.6585	-0.2938
AVISITN*TRTPN	3	900	-0.4832	0.09045	311	-5.34	<.0001	0.05	-0.6612	-0.3052
AVISITN*TRTPN	4	1	-0.8222	0.1088	306	-7.55	<.0001	0.05	-1.0364	-0.6080

SOURCE: MMRMOUT; TABLE: statlcgisa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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 PROTOCOL 331-201-00061

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Proc Mixed Output for Change [REDACTED] in CGI-S Scale, MMRM (UN)
 (Intent to Treat Sample)

STAT-5.1

Parameter Code=CGI0101

The Mixed Procedure

Least Squares Means

Effect	Analysis Visit (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
AVISITN*TRTPN	4	2	-0.6149	0.1154	311	-5.33	<.0001	0.05	-0.8419	-0.3879
AVISITN*TRTPN	4	3	-0.7613	0.1107	309	-6.88	<.0001	0.05	-0.9790	-0.5435
AVISITN*TRTPN	4	900	-0.6990	0.1079	304	-6.48	<.0001	0.05	-0.9112	-0.4867
AVISITN*TRTPN	6	1	-1.0538	0.1169	298	-9.01	<.0001	0.05	-1.2838	-0.8237
AVISITN*TRTPN	6	2	-0.7087	0.1241	310	-5.71	<.0001	0.05	-0.9529	-0.4646
AVISITN*TRTPN	6	3	-0.8362	0.1191	305	-7.02	<.0001	0.05	-1.0705	-0.6019
AVISITN*TRTPN	6	900	-0.7835	0.1137	289	-6.89	<.0001	0.05	-1.0073	-0.5598
AVISITN*TRTPN	8	1	-1.4308	0.1181	299	-12.11	<.0001	0.05	-1.6633	-1.1983
AVISITN*TRTPN	8	2	-0.9813	0.1255	314	-7.82	<.0001	0.05	-1.2283	-0.7343
AVISITN*TRTPN	8	3	-0.8745	0.1201	303	-7.28	<.0001	0.05	-1.1108	-0.6382
AVISITN*TRTPN	8	900	-1.0167	0.1144	290	-8.88	<.0001	0.05	-1.2420	-0.7915
AVISITN*TRTPN	10	1	-1.3465	0.1236	276	-10.89	<.0001	0.05	-1.5899	-1.1031
AVISITN*TRTPN	10	2	-1.0866	0.1346	303	-8.07	<.0001	0.05	-1.3516	-0.8217
AVISITN*TRTPN	10	3	-0.9306	0.1257	282	-7.40	<.0001	0.05	-1.1780	-0.6831
AVISITN*TRTPN	10	900	-0.8732	0.1209	279	-7.22	<.0001	0.05	-1.1111	-0.6352
AVISITN*TRTPN	12	1	-1.4426	0.1363	268	-10.58	<.0001	0.05	-1.7111	-1.1742
AVISITN*TRTPN	12	2	-1.1388	0.1478	285	-7.71	<.0001	0.05	-1.4297	-0.8479
AVISITN*TRTPN	12	3	-1.2181	0.1382	272	-8.82	<.0001	0.05	-1.4901	-0.9461
AVISITN*TRTPN	12	900	-1.0330	0.1325	268	-7.79	<.0001	0.05	-1.2939	-0.7721

SOURCE: MMRMOUT; TABLE: statlcgisa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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 PROTOCOL 331-201-00061

14 OF 14

Proc Mixed Output for Change [REDACTED] in CGI-S Scale, MMRM (UN)
 (Intent to Treat Sample)

STAT-5.1

Parameter Code=CGI0101

The Mixed Procedure

Tests of Effect Slices

Effect	Analysis Visit (N)	Num DF	Den DF	F Value	Pr > F
AVISITN*TRTPN	2	3	286	1.02	0.3838
AVISITN*TRTPN	3	3	293	1.05	0.3725
AVISITN*TRTPN	4	3	286	0.66	0.5772
AVISITN*TRTPN	6	3	280	1.63	0.1816
AVISITN*TRTPN	8	3	282	4.41	0.0047
AVISITN*TRTPN	10	3	268	3.08	0.0282
AVISITN*TRTPN	12	3	258	1.70	0.1682

SOURCE: MMRMOUT; TABLE: statlcgisa.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIRAZOLE
PROTOCOL 331-201-00061

1 OF 6

STAT-5.2
Proc GLM Output for Change [REDACTED] in CGI-S Scale, LOCF
(Intent to Treat Sample)

----- Parameter Code=CGI0101 Analysis Visit (N)=10 -----

The GLM Procedure

Class Level Information

Class	Levels	Values
TRTPN	4	1 2 3 900
POOLCNTR	10	[REDACTED]
COMBFL	2	N Y

Number of Observations Read 308
Number of Observations Used 308

SOURCE: GLMOUT; TABLE: stat1cgisb.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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PROTOCOL 331-201-00061

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STAT-5.2
Proc GLM Output for Change ██████████ in CGI-S Scale, LOCF
(Intent to Treat Sample)

----- Parameter Code=CGI0101 Analysis Visit (N)=10 -----					
The GLM Procedure					
Dependent Variable: CHG Change from Baseline					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	14	72.4586988	5.1756213	5.54	<.0001
Error	293	273.4893531	0.9334108		
Corrected Total	307	345.9480519			
R-Square	Coeff Var	Root MSE	CHG Mean		
0.209450	-97.88441	0.966132	-0.987013		
Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRTPN	3	9.04613251	3.01537750	3.23	0.0228
POOLCNTR	9	14.38413891	1.59823766	1.71	0.0857
COMBFL	1	0.22842769	0.22842769	0.24	0.6212
BASE	1	41.63627421	41.63627421	44.61	<.0001

SOURCE: GLMOUT; TABLE: statlcgisb.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIRAZOLE
PROTOCOL 331-201-00061

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STAT-5.2
Proc GLM Output for Change ██████████ in CGI-S Scale, LOCF
(Intent to Treat Sample)

----- Parameter Code=CGI0101 Analysis Visit (N)=10 -----

The GLM Procedure

Level of		-----CHG-----		-----BASE-----	
TRTPN	N	Mean	Std Dev	Mean	Std Dev
1	79	-1.27848101	1.09704392	4.41772152	0.85646254
2	72	-0.91666667	1.05816743	4.26388889	1.03451772
3	77	-0.88311688	1.02564519	4.37662338	0.97385508
900	80	-0.86250000	1.02800963	4.37500000	0.81714229

SOURCE: GLMOUT; TABLE: statlcgisb.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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BREXPIPIRAZOLE
 PROTOCOL 331-201-00061

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Proc GLM Output for Change XXXXXXXXXX STAT-5.2
 (Intent to Treat Sample) in CGI-S Scale, LOCF

 ----- Parameter Code=CGI0101 Analysis Visit (N)=10 -----

The GLM Procedure
 Least Squares Means

TRTPN	CHG LSMEAN	Standard Error	Pr > t	LSMEAN Number
1	-1.25672434	0.11660319	<.0001	1
2	-0.93411448	0.12539640	<.0001	2
3	-0.84629828	0.11943530	<.0001	3
900	-0.83938241	0.11714733	<.0001	4

Least Squares Means for effect TRTPN
 Pr > |t| for H0: LSMean(i)=LSMean(j)

Dependent Variable: CHG

i/j	1	2	3	4
1		0.0429	0.0088	0.0070
2	0.0429		0.5824	0.5484
3	0.0088	0.5824		0.9643
4	0.0070	0.5484	0.9643	

SOURCE: GLMOUT; TABLE: statlcgisb.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIPIRAZOLE STAT-5.2 FINAL

BREXPIRAZOLE
 PROTOCOL 331-201-00061

5 OF 6

Proc GLM Output for Change [REDACTED] in CGI-S Scale, LOCF
 (Intent to Treat Sample)

----- Parameter Code=CGI0101 Analysis Visit (N)=10 -----

The GLM Procedure
 Least Squares Means

TRTPN	CHG LSMEAN	95% Confidence Limits	
1	-1.256724	-1.486210	-1.027238
2	-0.934114	-1.180906	-0.687323
3	-0.846298	-1.081358	-0.611238
900	-0.839382	-1.069939	-0.608826

Least Squares Means for Effect TRTPN

i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.322610	-0.634789	-0.010430
1	3	-0.410426	-0.716610	-0.104242
1	4	-0.417342	-0.719558	-0.115126
2	3	-0.087816	-0.401810	0.226177
2	4	-0.094732	-0.405045	0.215581
3	4	-0.006916	-0.310973	0.297141

NOTE: To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

SOURCE: GLMOUT; TABLE: statlcgisb.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-5.2
Proc GLM Output for Change ██████████ in CGI-S Scale, LOCF
(Intent to Treat Sample)

----- Parameter Code=CGI0101 Analysis Visit (N)=10 -----

The GLM Procedure
Dependent Variable: CHG Change from Baseline

Parameter	Estimate	Standard Error	t Value	Pr > t
1 vs 900	-0.41734192	0.15355755	-2.72	0.0070
1 vs 3	-0.41042606	0.15557404	-2.64	0.0088
1 vs 2	-0.32260986	0.15862022	-2.03	0.0429
2 vs 900	-0.09473206	0.15767173	-0.60	0.5484
3 vs 900	-0.00691586	0.15449314	-0.04	0.9643

SOURCE: GLMOUT; TABLE: statlcgisb.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-5.2 FINAL

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BREXPIRAZOLE
PROTOCOL 331-201-00061

1 OF 6

STAT-5.3
Proc GLM Output for Change ██████████ in CGI-S Scale, OC
(Intent to Treat Sample)

----- Parameter Code=CGI0101 Analysis Visit (N)=10 -----

The GLM Procedure
Class Level Information

Class	Levels	Values
TRTPN	4	1 2 3 900

Number of Observations Read 308
Number of Observations Used 308

SOURCE: GLMOUT; TABLE: statlcgisc.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-5.3 FINAL

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Proc GLM Output for Change XXXXXXXXXX in CGI-S Scale, OC
 (Intent to Treat Sample)

----- Parameter Code=CGI0101 Analysis Visit (N)=10 -----					
The GLM Procedure					
Dependent Variable: CHG Change from Baseline					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	4	57.6739577	14.4184894	15.16	<.0001
Error	303	288.2740942	0.9513997		
Corrected Total	307	345.9480519			
R-Square Coeff Var Root MSE CHG Mean					
0.166713 -98.82313 0.975397 -0.987013					
Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRTPN	3	7.98612564	2.66204188	2.80	0.0403
BASE	1	48.53487543	48.53487543	51.01	<.0001

SOURCE: GLMOUT; TABLE: statlcgisc.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-5.3
Proc GLM Output for Change ██████████ in CGI-S Scale, OC
(Intent to Treat Sample)

----- Parameter Code=CGI0101 Analysis Visit (N)=10 -----

The GLM Procedure

Level of		-----CHG-----		-----BASE-----	
TRTPN	N	Mean	Std Dev	Mean	Std Dev
1	79	-1.27848101	1.09704392	4.41772152	0.85646254
2	72	-0.91666667	1.05816743	4.26388889	1.03451772
3	77	-0.88311688	1.02564519	4.37662338	0.97385508
900	80	-0.86250000	1.02800963	4.37500000	0.81714229

SOURCE: GLMOUT; TABLE: statlcgisc.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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Proc GLM Output for Change [REDACTED] in CGI-S Scale, OC
 (Intent to Treat Sample)

----- Parameter Code=CGI0101 Analysis Visit (N)=10 -----

The GLM Procedure
 Least Squares Means

TRTPN	CHG LSMEAN	Standard Error	Pr > t	LSMEAN Number
1	-1.25361599	0.10979596	<.0001	1
2	-0.95851933	0.11510091	<.0001	2
3	-0.87607625	0.11116120	<.0001	3
900	-0.85616343	0.10905633	<.0001	4

Least Squares Means for effect TRTPN
 Pr > |t| for H0: LSMean(i)=LSMean(j)

Dependent Variable: CHG

i/j	1	2	3	4
1		0.0648	0.0163	0.0107
2	0.0648		0.6069	0.5192
3	0.0163	0.6069		0.8983
4	0.0107	0.5192	0.8983	

SOURCE: GLMOUT; TABLE: statlcgisc.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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5 OF 6

Proc GLM Output for Change [REDACTED] in CGI-S Scale, OC
 (Intent to Treat Sample)

----- Parameter Code=CGI0101 Analysis Visit (N)=10 -----				
The GLM Procedure				
Least Squares Means				
TRTPN	CHG	LSMEAN	95% Confidence Limits	
1		-1.253616	-1.469675	-1.037557
2		-0.958519	-1.185018	-0.732021
3		-0.876076	-1.094822	-0.657331
900		-0.856163	-1.070767	-0.641560
Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.295097	-0.608371	0.018178
1	3	-0.377540	-0.684956	-0.070124
1	4	-0.397453	-0.701940	-0.092966
2	3	-0.082443	-0.397397	0.232511
2	4	-0.102356	-0.414440	0.209728
3	4	-0.019913	-0.326340	0.286514

NOTE: To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

SOURCE: GLMOUT; TABLE: statlcgisc.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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6 OF 6

STAT-5.3
Proc GLM Output for Change ██████████ in CGI-S Scale, OC
(Intent to Treat Sample)

----- Parameter Code=CGI0101 Analysis Visit (N)=10 -----

The GLM Procedure
Dependent Variable: CHG Change from Baseline

Parameter	Estimate	Standard Error	t Value	Pr > t
1 vs 900	-0.39745256	0.15473286	-2.57	0.0107
1 vs 3	-0.37753974	0.15622132	-2.42	0.0163
1 vs 2	-0.29509666	0.15919853	-1.85	0.0648
2 vs 900	-0.10235590	0.15859351	-0.65	0.5192
3 vs 900	-0.01991282	0.15571880	-0.13	0.8983

SOURCE: GLMOUT; TABLE: statlcgisc.lis; RUN: 05FEB2019 14:05; ANALYSIS DATASET CREATED: 05FEB2019 11:24
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/stat1.sas
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STAT-6.1.1

Shapiro-Wilk Test for Residual by Week from Proc Mixed for Change from [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Mode
(Intent to Treat Sample)

PROTOCOL	Week	TEST VARIABLE	GOODNESS OF FIT TEST	GOODNESS OF FIT	
				TEST STATISTICS	Pvalue
33120100061	WEEK 3	RESID	Shapiro-Wilk	0.9882	0.0182
		STUDENTRESID	Shapiro-Wilk	0.9883	0.0188
	WEEK 6	RESID	Shapiro-Wilk	0.9955	0.6767
		STUDENTRESID	Shapiro-Wilk	0.9957	0.7080
	WEEK 10	RESID	Shapiro-Wilk	0.9938	0.4650
		STUDENTRESID	Shapiro-Wilk	0.9939	0.4915
	WEEK 12	RESID	Shapiro-Wilk	0.9904	0.1438
		STUDENTRESID	Shapiro-Wilk	0.9905	0.1519

FILE: normality_ba.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality_b.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The UNIVARIATE Procedure
Variable: RESID (Residual)

Moments

N	291	Sum Weights	291
Mean	-0.0214753	Sum Observations	-6.2493044
Std Deviation	8.65090319	Variance	74.838126
Skewness	-0.2970035	Kurtosis	0.70012695
Uncorrected SS	21703.1908	Corrected SS	21703.0565
Coeff Variation	-40283.089	Std Error Mean	0.50712493

Basic Statistical Measures

Location		Variability	
Mean	-0.02148	Std Deviation	8.65090
Median	0.64232	Variance	74.83813
Mode	-4.37399	Range	59.42843
		Interquartile Range	10.54517

Note: The mode displayed is the smallest of 2 modes with a count of 2.

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-6.1.2 FINAL

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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The UNIVARIATE Procedure
Variable: RESID (Residual)

Tests for Location: Mu0=0

Test	-Statistic-	-----p Value-----
Student's t	t -0.04235	Pr > t 0.9663
Sign	M 10.5	Pr >= M 0.2410
Signed Rank	S 694	Pr >= S 0.6299

Tests for Normality

Test	--Statistic---	-----p Value-----
Shapiro-Wilk	W 0.988221	Pr < W 0.0182
Kolmogorov-Smirnov	D 0.042805	Pr > D >0.1500
Cramer-von Mises	W-Sq 0.127591	Pr > W-Sq 0.0479
Anderson-Darling	A-Sq 0.815848	Pr > A-Sq 0.0364

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The UNIVARIATE Procedure
Variable: RESID (Residual)

Quantiles (Definition 5)

Level	Quantile
100% Max	31.498902
99%	16.876065
95%	13.771516
90%	10.384727
75% Q3	5.476349
50% Median	0.642323
25% Q1	-5.068825
10%	-11.778869
5%	-15.393540
1%	-26.106596
0% Min	-27.929524

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-6.1.2 FINAL

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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The UNIVARIATE Procedure
Variable: RESID (Residual)

Extreme Observations

-----Lowest-----			-----Highest-----		
Value	USUBJID	Obs	Value	USUBJID	Obs
-27.9295	[REDACTED]	132	16.3999	[REDACTED]	54
-26.3621	[REDACTED]	198	16.6089	[REDACTED]	125
-26.1066	[REDACTED]	274	16.8761	[REDACTED]	224
-21.2636	[REDACTED]	92	19.4553	[REDACTED]	196
-21.2002	[REDACTED]	248	31.4989	[REDACTED]	254

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)

Moments

N	291	Sum Weights	291
Mean	-0.0024051	Sum Observations	-0.6998929
Std Deviation	1.00383089	Variance	1.00767645
Skewness	-0.2968518	Kurtosis	0.69179846
Uncorrected SS	292.227853	Corrected SS	292.226169
Coeff Variation	-41737.07	Std Error Mean	0.05884561

Basic Statistical Measures

Location		Variability	
Mean	-0.00241	Std Deviation	1.00383
Median	0.07393	Variance	1.00768
Mode	-0.50179	Range	6.86481
		Interquartile Range	1.22110

Note: The mode displayed is the smallest of 2 modes with a count of 2.

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)

Tests for Location: Mu0=0

Test	-Statistic-	-----p Value-----
Student's t	t -0.04087	Pr > t 0.9674
Sign	M 10.5	Pr >= M 0.2410
Signed Rank	S 688	Pr >= S 0.6328

Tests for Normality

Test	--Statistic--	-----p Value-----
Shapiro-Wilk	W 0.988289	Pr < W 0.0188
Kolmogorov-Smirnov	D 0.043362	Pr > D >0.1500
Cramer-von Mises	W-Sq 0.128135	Pr > W-Sq 0.0473
Anderson-Darling	A-Sq 0.816711	Pr > A-Sq 0.0362

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)

Quantiles (Definition 5)

Level	Quantile
100% Max	3.6431135
99%	1.9692294
95%	1.6004374
90%	1.1991299
75% Q3	0.6349279
50% Median	0.0739303
25% Q1	-0.5861709
10%	-1.3663926
5%	-1.7824894
1%	-3.0219158
0% Min	-3.2216923

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=3 -----

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)

Extreme Observations

-----Lowest-----			-----Highest-----		
Value	USUBJID	Obs	Value	USUBJID	Obs
-3.22169	[REDACTED]	132	1.89560	[REDACTED]	54
-3.05977	[REDACTED]	198	1.93905	[REDACTED]	125
-3.02192	[REDACTED]	274	1.96923	[REDACTED]	224
-2.50633	[REDACTED]	92	2.25031	[REDACTED]	196
-2.45764	[REDACTED]	248	3.64311	[REDACTED]	254

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
 Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
 (Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The UNIVARIATE Procedure
 Variable: RESID (Residual)

Moments

N	254	Sum Weights	254
Mean	0.44348967	Sum Observations	112.646377
Std Deviation	10.3794296	Variance	107.732559
Skewness	-0.0610478	Kurtosis	-0.1779101
Uncorrected SS	27306.2949	Corrected SS	27256.3374
Coeff Variation	2340.39939	Std Error Mean	0.65126334

Basic Statistical Measures

Location		Variability	
Mean	0.44349	Std Deviation	10.37943
Median	-0.35614	Variance	107.73256
Mode	-7.53665	Range	57.11948
		Interquartile Range	15.34328

Note: The mode displayed is the smallest of 2 modes with a count of 2.

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The UNIVARIATE Procedure
Variable: RESID (Residual)

Tests for Location: Mu0=0

Test	-Statistic-	-----p Value-----
Student's t	t 0.680968	Pr > t 0.4965
Sign	M -3	Pr >= M 0.7538
Signed Rank	S 780.5	Pr >= S 0.5065

Tests for Normality

Test	--Statistic--	-----p Value-----
Shapiro-Wilk	W 0.995535	Pr < W 0.6767
Kolmogorov-Smirnov	D 0.03977	Pr > D >0.1500
Cramer-von Mises	W-Sq 0.06535	Pr > W-Sq >0.2500
Anderson-Darling	A-Sq 0.365198	Pr > A-Sq >0.2500

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-6.1.2 FINAL

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STAT-6.1.2
Residual by Week from Proc Mixed for Change ██████████ in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The UNIVARIATE Procedure
Variable: RESID (Residual)

Quantiles (Definition 5)

Level	Quantile
100% Max	27.384452
99%	24.503200
95%	16.489434
90%	13.817986
75% Q3	8.448887
50% Median	-0.356136
25% Q1	-6.894394
10%	-13.388430
5%	-17.101553
1%	-23.196941
0% Min	-29.735033

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The UNIVARIATE Procedure
Variable: RESID (Residual)

Extreme Observations

-----Lowest-----			-----Highest-----		
Value	USUBJID	Obs	Value	USUBJID	Obs
-29.7350	[REDACTED]	507	23.4238	[REDACTED]	513
-28.9422	[REDACTED]	340	24.4231	[REDACTED]	294
-23.1969	[REDACTED]	363	24.5032	[REDACTED]	544
-20.2321	[REDACTED]	450	25.4941	[REDACTED]	332
-20.1481	[REDACTED]	444	27.3845	[REDACTED]	408

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-6.1.2 FINAL

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STAT-6.1.2
 Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
 (Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The UNIVARIATE Procedure
 Variable: STUDENTRESID (Studentized Residual)

Moments

N	254	Sum Weights	254
Mean	0.04293573	Sum Observations	10.9056744
Std Deviation	0.99698457	Variance	0.99397824
Skewness	-0.0557595	Kurtosis	-0.1703408
Uncorrected SS	251.944738	Corrected SS	251.476495
Coeff Variation	2322.03962	Std Error Mean	0.06255638

Basic Statistical Measures

Location		Variability	
Mean	0.04294	Std Deviation	0.99698
Median	-0.03408	Variance	0.99398
Mode	-0.71999	Range	5.49119
		Interquartile Range	1.48157

Note: The mode displayed is the smallest of 2 modes with a count of 2.

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)

Tests for Location: Mu0=0

Test	-Statistic-	-----p Value-----
Student's t	t 0.686353	Pr > t 0.4931
Sign	M -3	Pr >= M 0.7538
Signed Rank	S 776.5	Pr >= S 0.5087

Tests for Normality

Test	--Statistic--	-----p Value-----
Shapiro-Wilk	W 0.995702	Pr < W 0.7080
Kolmogorov-Smirnov	D 0.038935	Pr > D >0.1500
Cramer-von Mises	W-Sq 0.064256	Pr > W-Sq >0.2500
Anderson-Darling	A-Sq 0.355152	Pr > A-Sq >0.2500

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-6.1.2 FINAL

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STAT-6.1.2
Residual by Week from Proc Mixed for Change ██████████ in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)

Quantiles (Definition 5)

Level	Quantile
100% Max	2.6341119
99%	2.3834988
95%	1.5884046
90%	1.3306425
75% Q3	0.8085245
50% Median	-0.0340834
25% Q1	-0.6730415
10%	-1.2880822
5%	-1.6340538
1%	-2.2490702
0% Min	-2.8570808

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-6.1.2 FINAL

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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=6 -----

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)

Extreme Observations

-----Lowest-----			-----Highest-----		
Value	USUBJID	Obs	Value	USUBJID	Obs
-2.85708	[REDACTED]	507	2.25072	[REDACTED]	513
-2.77159	[REDACTED]	340	2.32984	[REDACTED]	294
-2.24907	[REDACTED]	363	2.38350	[REDACTED]	544
-1.93758	[REDACTED]	450	2.45627	[REDACTED]	332
-1.92494	[REDACTED]	444	2.63411	[REDACTED]	408

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-6.1.2 FINAL

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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The UNIVARIATE Procedure
Variable: RESID (Residual)

Moments

N	227	Sum Weights	227
Mean	0.08611581	Sum Observations	19.5482882
Std Deviation	10.6826629	Variance	114.119287
Skewness	-0.1828243	Kurtosis	-0.146025
Uncorrected SS	25792.6423	Corrected SS	25790.9589
Coeff Variation	12404.9966	Std Error Mean	0.70903324

Basic Statistical Measures

Location		Variability	
Mean	0.08612	Std Deviation	10.68266
Median	-0.06010	Variance	114.11929
Mode	-5.59726	Range	58.82853
		Interquartile Range	14.39574

Note: The mode displayed is the smallest of 2 modes with a count of 2.

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The UNIVARIATE Procedure
Variable: RESID (Residual)

Tests for Location: Mu0=0

Test	-Statistic-	-----p Value-----
Student's t	t 0.121455	Pr > t 0.9034
Sign	M -0.5	Pr >= M 1.0000
Signed Rank	S 291	Pr >= S 0.7697

Tests for Normality

Test	--Statistic--	-----p Value-----
Shapiro-Wilk	W 0.993767	Pr < W 0.4650
Kolmogorov-Smirnov	D 0.033884	Pr > D >0.1500
Cramer-von Mises	W-Sq 0.038705	Pr > W-Sq >0.2500
Anderson-Darling	A-Sq 0.300666	Pr > A-Sq >0.2500

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change ██████████ in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The UNIVARIATE Procedure
Variable: RESID (Residual)

Quantiles (Definition 5)

Level	Quantile
100% Max	25.824025
99%	22.779706
95%	17.026880
90%	14.368205
75% Q3	7.330122
50% Median	-0.060104
25% Q1	-7.065623
10%	-13.686490
5%	-18.354843
1%	-24.242300
0% Min	-33.004507

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The UNIVARIATE Procedure
Variable: RESID (Residual)

Extreme Observations

-----Lowest-----			-----Highest-----		
Value	USUBJID	Obs	Value	USUBJID	Obs
-33.0045	[REDACTED]	565	20.3750	[REDACTED]	650
-24.5363	[REDACTED]	708	21.9446	[REDACTED]	566
-24.2423	[REDACTED]	553	22.7797	[REDACTED]	619
-24.1066	[REDACTED]	589	22.8236	[REDACTED]	614
-23.2337	[REDACTED]	645	25.8240	[REDACTED]	764

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-6.1.2 FINAL

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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)

Moments

N	227	Sum Weights	227
Mean	0.00806674	Sum Observations	1.831149
Std Deviation	0.97676522	Variance	0.95407029
Skewness	-0.1794597	Kurtosis	-0.1289175
Uncorrected SS	215.634657	Corrected SS	215.619886
Coeff Variation	12108.5562	Std Error Mean	0.06483018

Basic Statistical Measures

Location		Variability	
Mean	0.00807	Std Deviation	0.97677
Median	-0.00547	Variance	0.95407
Mode	-0.50932	Range	5.40570
		Interquartile Range	1.31622

Note: The mode displayed is the smallest of 2 modes with a count of 2.

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)

Tests for Location: Mu0=0

Test	-Statistic-	-----p Value-----
Student's t	t 0.124429	Pr > t 0.9011
Sign	M -0.5	Pr >= M 1.0000
Signed Rank	S 290	Pr >= S 0.7704

Tests for Normality

Test	--Statistic--	-----p Value-----
Shapiro-Wilk	W 0.993944	Pr < W 0.4915
Kolmogorov-Smirnov	D 0.033338	Pr > D >0.1500
Cramer-von Mises	W-Sq 0.038046	Pr > W-Sq >0.2500
Anderson-Darling	A-Sq 0.292192	Pr > A-Sq >0.2500

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)

Quantiles (Definition 5)

Level	Quantile
100% Max	2.35327141
99%	2.11123783
95%	1.55962015
90%	1.31465170
75% Q3	0.67188649
50% Median	-0.00547028
25% Q1	-0.64433297
10%	-1.24754229
5%	-1.67961704
1%	-2.20347197
0% Min	-3.05242422

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-6.1.2 FINAL

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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=10 -----

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)

Extreme Observations

-----Lowest-----			-----Highest-----		
Value	USUBJID	Obs	Value	USUBJID	Obs
-3.05242	[REDACTED]	565	1.86278	[REDACTED]	650
-2.23710	[REDACTED]	708	2.02821	[REDACTED]	566
-2.20347	[REDACTED]	553	2.11124	[REDACTED]	614
-2.19831	[REDACTED]	589	2.11717	[REDACTED]	619
-2.11381	[REDACTED]	645	2.35327	[REDACTED]	764

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-6.1.2 FINAL

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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The UNIVARIATE Procedure
Variable: RESID (Residual)

Moments

N	224	Sum Weights	224
Mean	-0.060841	Sum Observations	-13.628393
Std Deviation	11.7505394	Variance	138.075175
Skewness	0.03467632	Kurtosis	-0.5270157
Uncorrected SS	30791.5933	Corrected SS	30790.7641
Coeff Variation	-19313.509	Std Error Mean	0.78511594

Basic Statistical Measures

Location		Variability	
Mean	-0.06084	Std Deviation	11.75054
Median	-0.40775	Variance	138.07518
Mode	14.65028	Range	58.81038
		Interquartile Range	17.57915

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The UNIVARIATE Procedure
Variable: RESID (Residual)

Tests for Location: Mu0=0

Test	-Statistic-	-----p Value-----
Student's t	t -0.07749	Pr > t 0.9383
Sign	M -2	Pr >= M 0.8412
Signed Rank	S -143	Pr >= S 0.8833

Tests for Normality

Test	--Statistic--	-----p Value-----
Shapiro-Wilk	W 0.990386	Pr < W 0.1438
Kolmogorov-Smirnov	D 0.046115	Pr > D >0.1500
Cramer-von Mises	W-Sq 0.102955	Pr > W-Sq 0.1031
Anderson-Darling	A-Sq 0.621895	Pr > A-Sq 0.1050

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-6.1.2 FINAL

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STAT-6.1.2
Residual by Week from Proc Mixed for Change ██████████ in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The UNIVARIATE Procedure
Variable: RESID (Residual)

Quantiles (Definition 5)

Level	Quantile
100% Max	26.15988
99%	24.90444
95%	20.02366
90%	15.90305
75% Q3	9.17140
50% Median	-0.40775
25% Q1	-8.40775
10%	-14.86161
5%	-17.45916
1%	-24.00422
0% Min	-32.65050

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The UNIVARIATE Procedure
Variable: RESID (Residual)

Extreme Observations

-----Lowest-----			-----Highest-----		
Value	USUBJID	Obs	Value	USUBJID	Obs
-32.6505	[REDACTED]	797	22.4025	[REDACTED]	979
-29.7432	[REDACTED]	793	22.4483	[REDACTED]	994
-24.0042	[REDACTED]	871	24.9044	[REDACTED]	847
-23.3489	[REDACTED]	780	25.3498	[REDACTED]	921
-23.2061	[REDACTED]	816	26.1599	[REDACTED]	794

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)

Moments

N	224	Sum Weights	224
Mean	-0.0049909	Sum Observations	-1.1179516
Std Deviation	0.98854745	Variance	0.97722606
Skewness	0.03317158	Kurtosis	-0.5106489
Uncorrected SS	217.926991	Corrected SS	217.921412
Coeff Variation	-19807.175	Std Error Mean	0.0660501

Basic Statistical Measures

Location		Variability	
Mean	-0.00499	Std Deviation	0.98855
Median	-0.03454	Variance	0.97723
Mode	1.22405	Range	4.99503
		Interquartile Range	1.47852

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-6.1.2 FINAL

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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)

Tests for Location: Mu0=0

Test	-Statistic-	-----p Value-----
Student's t	t -0.07556	Pr > t 0.9398
Sign	M -2	Pr >= M 0.8412
Signed Rank	S -147	Pr >= S 0.8801

Tests for Normality

Test	--Statistic---	-----p Value-----
Shapiro-Wilk	W 0.990531	Pr < W 0.1519
Kolmogorov-Smirnov	D 0.045559	Pr > D >0.1500
Cramer-von Mises	W-Sq 0.102583	Pr > W-Sq 0.1046
Anderson-Darling	A-Sq 0.620048	Pr > A-Sq 0.1063

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-6.1.2 FINAL

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STAT-6.1.2
Residual by Week from Proc Mixed for Change ██████████ in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)

Quantiles (Definition 5)

Level	Quantile
100% Max	2.2200513
99%	2.1274494
95%	1.6918552
90%	1.3461309
75% Q3	0.7703818
50% Median	-0.0345376
25% Q1	-0.7081358
10%	-1.2443432
5%	-1.4710086
1%	-2.0101286
0% Min	-2.7749833

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/normality.sas
OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT-6.1.2 FINAL

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BREXPIRAZOLE
PROTOCOL 331-201-00061

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STAT-6.1.2
Residual by Week from Proc Mixed for Change [REDACTED] in CAPS-5 Total Score, Primary Efficacy Analysis Model
(Intent to Treat Sample)

----- Analysis Visit (N)=12 -----

The UNIVARIATE Procedure
Variable: STUDENTRESID (Studentized Residual)

Extreme Observations

-----Lowest-----			-----Highest-----		
Value	USUBJID	Obs	Value	USUBJID	Obs
-2.77498	[REDACTED]	797	1.87914	[REDACTED]	979
-2.52653	[REDACTED]	793	1.88518	[REDACTED]	994
-2.01013	[REDACTED]	871	2.12745	[REDACTED]	847
-1.95439	[REDACTED]	780	2.12941	[REDACTED]	921
-1.94802	[REDACTED]	816	2.22005	[REDACTED]	794

FILE: normalitybc.lis, RUN: 05FEB2019 14:05
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BREXPIPIRAZOLE
 PROTOCOL 331-201-00061

1 OF 13

Adjusted Mean Change [REDACTED] STAT1-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

CAPS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹				
CAPSW-INTRUSIVE MEMORIES SEVERITY	58	2.48	-1.27	48	2.44	-0.92	59	2.51	-0.67	59	2.31	-1.03	Dummy W vs Dummy Z	-0.24	0.3345	-0.18
													Dummy W vs Dummy Y	-0.60	0.0176	-0.44
													Dummy W vs Dummy X	-0.35	0.1931	-0.25
													Dummy X vs Dummy Z	0.11	0.6864	0.08
													Dummy Y vs Dummy Z	0.36	0.1527	0.26
CAPSW-DISTRESSI NG DREAMS SEVERITY	58	1.29	-0.72	48	1.85	-0.68	59	1.92	-0.60	59	1.75	-0.71	Dummy W vs Dummy Z	-0.01	0.9610	-0.01
													Dummy W vs Dummy Y	-0.12	0.6182	-0.09
													Dummy W vs Dummy X	-0.04	0.8828	-0.03
													Dummy X vs Dummy Z	0.03	0.9174	0.02
													Dummy Y vs Dummy Z	0.11	0.6478	0.08
CAPSW-DISSOCIAT IVE REACTIONS SEVERITY	58	0.98	-0.75	48	0.92	-0.42	59	0.88	-0.37	59	1.02	-0.59	Dummy W vs Dummy Z	-0.16	0.3968	-0.16
													Dummy W vs Dummy Y	-0.38	0.0461	-0.37
													Dummy W vs Dummy X	-0.33	0.1101	-0.31
													Dummy X vs Dummy Z	0.17	0.4118	0.16
													Dummy Y vs Dummy Z	0.22	0.2442	0.22

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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 PROGRAM: /opt/sas/Data/DAP/OPC34712/P33120100061/STAT/Program.dev/DOC_STAT/caps_itemm.sas
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BREXPIRAZOLE
 PROTOCOL 331-201-00061

2 OF 13

Adjusted Mean Change [REDACTED] STAT1-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

CAPS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
CAPSW-CUED PSYCHOLOGICAL DISTRESS SEVERITY	58	2.50	-1.25	48	2.38	-1.08	59	2.39	-0.84	59	2.39	-1.04	Dummy W vs Dummy Z	-0.21	0.3861	-0.16
													Dummy W vs Dummy Y	-0.41	0.0934	-0.31
													Dummy W vs Dummy X	-0.17	0.5262	-0.12
													Dummy X vs Dummy Z	-0.05	0.8623	-0.03
													Dummy Y vs Dummy Z	0.20	0.4095	0.15
CAPSW-CUED PSYCHOLOGICAL REACTION SEVERITY	58	2.33	-1.29	48	2.27	-1.10	59	2.31	-0.44	59	2.37	-0.73	Dummy W vs Dummy Z	-0.56	0.0232	-0.42
													Dummy W vs Dummy Y	-0.84	0.0007	-0.64
													Dummy W vs Dummy X	-0.18	0.4800	-0.14
													Dummy X vs Dummy Z	-0.37	0.1539	-0.28
													Dummy Y vs Dummy Z	0.29	0.2365	0.22
CAPSW-AVOID MEM THGHTS FEELINGS SEVERITY	58	2.55	-1.09	48	2.52	-0.75	59	2.58	-0.58	59	2.58	-0.92	Dummy W vs Dummy Z	-0.17	0.4810	-0.13
													Dummy W vs Dummy Y	-0.50	0.0347	-0.39

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

3 OF 13

Adjusted Mean Change [REDACTED] STAT1-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

CAPS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹				
CAPSW-AVOID MEM THGHTS FEELNGS SEVERITY													Dummy W vs Dummy X	-0.34	0.1828	-0.26
													Dummy X vs Dummy Z	0.17	0.4945	0.13
													Dummy Y vs Dummy Z	0.34	0.1532	0.26
CAPSW-AVOID EXTERNL REMINDRS SEVERITY	58	2.47	-1.10	48	2.54	-0.95	59	2.51	-0.74	59	2.46	-0.89	Dummy W vs Dummy Z	-0.21	0.3875	-0.16
													Dummy W vs Dummy Y	-0.36	0.1418	-0.27
													Dummy W vs Dummy X	-0.15	0.5723	-0.11
													Dummy X vs Dummy Z	-0.06	0.8080	-0.05
													Dummy Y vs Dummy Z	0.15	0.5389	0.11
CAPSW-INABLT RECAL ASPCT EVNT SEVERITY	58	0.91	-0.22	48	0.96	-0.12	59	0.64	-0.10	59	0.64	-0.29	Dummy W vs Dummy Z	0.06	0.6355	0.09
													Dummy W vs Dummy Y	-0.12	0.3719	-0.17
													Dummy W vs Dummy X	-0.11	0.4578	-0.15
													Dummy X vs Dummy Z	0.17	0.2356	0.23
													Dummy Y vs Dummy Z	0.18	0.1681	0.25

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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BREXPIPIRAZOLE
 PROTOCOL 331-201-00061

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Adjusted Mean Change [REDACTED] STAT1-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

CAPS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹				
CAPSW-EXGGRTD NEG BELIFS EXPTNS SEVERITY	58	2.50	-1.13	48	2.56	-0.61	59	2.49	-0.86	59	2.24	-0.61	Dummy W vs Dummy Z	-0.52	0.0252	-0.42
													Dummy W vs Dummy Y	-0.27	0.2407	-0.22
													Dummy W vs Dummy X	-0.52	0.0365	-0.41
													Dummy X vs Dummy Z	0.00	0.9995	0.00
													Dummy Y vs Dummy Z	-0.25	0.2806	-0.20
CAPSW-DIST COGTNS LEADNG BLAME SEVERITY	58	2.00	-0.90	48	1.69	-0.84	59	2.14	-0.79	59	1.61	-0.75	Dummy W vs Dummy Z	-0.15	0.5172	-0.12
													Dummy W vs Dummy Y	-0.10	0.6433	-0.09
													Dummy W vs Dummy X	-0.05	0.8239	-0.04
													Dummy X vs Dummy Z	-0.09	0.6950	-0.08
													Dummy Y vs Dummy Z	-0.04	0.8480	-0.04
CAPSW-PRSISTNT NEG EMOTNL STATE SEVERITY	58	2.36	-0.98	48	2.69	-0.94	59	2.51	-0.84	59	2.41	-0.59	Dummy W vs Dummy Z	-0.39	0.0802	-0.33
													Dummy W vs Dummy Y	-0.14	0.5336	-0.12
													Dummy W vs Dummy X	-0.05	0.8461	-0.04
													Dummy X vs Dummy Z	-0.34	0.1536	-0.28
													Dummy Y vs Dummy Z	-0.25	0.2580	-0.21

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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BREXPIRAZOLE
 PROTOCOL 331-201-00061

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Adjusted Mean Change [REDACTED] STAT1-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

CAPS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹		P-VALUE ¹		
CAPSW-DIMISHD INTRST ACTVTIES SEVERITY	58	2.38	-1.31	48	2.42	-0.73	59	2.44	-0.59	59	2.27	-0.80	Dummy W vs Dummy Z	-0.51	0.0334	-0.40
													Dummy W vs Dummy Y	-0.72	0.0029	-0.56
													Dummy W vs Dummy X	-0.58	0.0240	-0.44
													Dummy X vs Dummy Z	0.07	0.7778	0.05
													Dummy Y vs Dummy Z	0.21	0.3769	0.16
CAPSW-DETACHMNT ESTRNGMNT OTHS SEVERITY	58	2.64	-0.96	48	2.40	-0.83	59	2.63	-0.64	59	2.59	-0.60	Dummy W vs Dummy Z	-0.36	0.1606	-0.26
													Dummy W vs Dummy Y	-0.32	0.2120	-0.23
													Dummy W vs Dummy X	-0.13	0.6469	-0.09
													Dummy X vs Dummy Z	-0.23	0.3969	-0.17
													Dummy Y vs Dummy Z	-0.04	0.8804	-0.03
CAPSW-PRERSISTNT INAB EXP POSTVE SEVERITY	58	2.16	-1.10	48	1.92	-0.62	59	2.02	-0.54	59	1.93	-0.58	Dummy W vs Dummy Z	-0.52	0.0234	-0.42
													Dummy W vs Dummy Y	-0.55	0.0164	-0.45
													Dummy W vs Dummy X	-0.48	0.0525	-0.38
													Dummy X vs Dummy Z	-0.04	0.8656	-0.03

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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BREXPIPIRAZOLE
 PROTOCOL 331-201-00061

6 OF 13

Adjusted Mean Change [REDACTED] STAT1-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

CAPS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN'S D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹				
CAPSW-PRISISTNT INAB EXP POSTVE SEVERITY													Dummy Y vs Dummy Z	0.03	0.8857	0.03
CAPSW-IRRITBLE BEHAV ANGRY SEVERITY	58	1.60	-0.42	48	1.67	-0.47	59	1.66	-0.49	59	1.69	-0.42	Dummy W vs Dummy Z	-0.00	0.9948	-0.00
													Dummy W vs Dummy Y	0.07	0.7672	0.05
													Dummy W vs Dummy X	0.04	0.8630	0.03
													Dummy X vs Dummy Z	-0.04	0.8573	-0.04
													Dummy Y vs Dummy Z	-0.07	0.7608	-0.06
CAPSW-RECKLS SELF DESTR BEHAV SEVERITY	58	0.33	-0.14	48	0.35	-0.11	59	0.22	-0.17	59	0.39	-0.11	Dummy W vs Dummy Z	-0.03	0.7718	-0.05
													Dummy W vs Dummy Y	0.03	0.7834	0.05
													Dummy W vs Dummy X	-0.03	0.7975	-0.05
													Dummy X vs Dummy Z	-0.00	0.9907	-0.00
													Dummy Y vs Dummy Z	-0.06	0.5707	-0.10
CAPSW-HYPERVIGI LANCE SEVERITY	58	2.64	-0.88	48	2.48	-0.55	59	2.29	-0.70	59	2.58	-0.48	Dummy W vs Dummy Z	-0.40	0.0622	-0.35
													Dummy W vs Dummy Y	-0.18	0.4040	-0.15

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIPIRAZOLE STAT1-1.1 FINAL

BREXPIRAZOLE
 PROTOCOL 331-201-00061

7 OF 13

Adjusted Mean Change [REDACTED] STAT1-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

CAPS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹				
CAPSW-HYPERVIGI LANCE SEVERITY													Dummy W vs Dummy X	-0.33	0.1518	-0.28
													Dummy X vs Dummy Z	-0.07	0.7578	-0.06
													Dummy Y vs Dummy Z	-0.22	0.3090	-0.19
CAPSW-EXAGGERAT D STRTLE RESPNSE SEVERITY	58	1.66	-0.52	48	1.65	-0.45	59	1.63	-0.59	59	1.54	-0.44	Dummy W vs Dummy Z	-0.08	0.7173	-0.07
													Dummy W vs Dummy Y	0.07	0.7553	0.06
													Dummy W vs Dummy X	-0.07	0.7608	-0.06
													Dummy X vs Dummy Z	-0.01	0.9741	-0.01
													Dummy Y vs Dummy Z	-0.15	0.4986	-0.12
CAPSW-PRBLMS WTH CONCENTRATION SEVERITY	58	2.34	-0.84	48	2.50	-0.68	59	2.10	-0.67	59	2.29	-0.76	Dummy W vs Dummy Z	-0.08	0.6973	-0.07
													Dummy W vs Dummy Y	-0.17	0.4292	-0.15
													Dummy W vs Dummy X	-0.17	0.4789	-0.14
													Dummy X vs Dummy Z	0.08	0.7269	0.07
													Dummy Y vs Dummy Z	0.09	0.6822	0.08

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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BREXPIRAZOLE
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Adjusted Mean Change [REDACTED] STAT1-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

CAPS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹				
CAPSW-SLEEP DISTURBANCE SEVERITY	58	2.33	-0.72	48	2.71	-0.74	59	2.68	-0.32	59	2.80	-0.52	Dummy W vs Dummy Z	-0.20	0.4206	-0.15
													Dummy W vs Dummy Y	-0.40	0.1014	-0.30
													Dummy W vs Dummy X	0.02	0.9315	0.02
													Dummy X vs Dummy Z	-0.22	0.3905	-0.17
													Dummy Y vs Dummy Z	0.20	0.3987	0.16
CAPSW-SUBJECTIV E DISTRESS SEVERITY	58	2.67	-0.96	48	2.75	-0.72	59	2.66	-0.60	59	2.53	-0.69	Dummy W vs Dummy Z	-0.27	0.0872	-0.32
													Dummy W vs Dummy Y	-0.36	0.0214	-0.43
													Dummy W vs Dummy X	-0.24	0.1538	-0.28
													Dummy X vs Dummy Z	-0.03	0.8527	-0.04
													Dummy Y vs Dummy Z	0.09	0.5545	0.11
CAPSW-IMPAIRMNT SOCIAL FUNCTNG SEVERITY	58	2.71	-1.14	48	2.60	-0.90	59	2.73	-0.70	59	2.58	-0.72	Dummy W vs Dummy Z	-0.42	0.0283	-0.41
													Dummy W vs Dummy Y	-0.44	0.0219	-0.43
													Dummy W vs Dummy X	-0.24	0.2348	-0.23
													Dummy X vs Dummy Z	-0.18	0.3824	-0.17
													Dummy Y vs Dummy Z	0.02	0.9146	0.02

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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BREXPIRAZOLE
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Adjusted Mean Change [REDACTED] STAT1-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

CAPS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN'S D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹		P-VALUE ¹		
CAPSW-IMPAIRMENT OCCUP FUNCTIONING SEVERITY	58	2.36	-0.77	48	2.31	-0.71	59	2.44	-0.59	59	2.29	-0.52	Dummy W vs Dummy Z	-0.25	0.2044	-0.24
													Dummy W vs Dummy Y	-0.18	0.3560	-0.17
													Dummy W vs Dummy X	-0.06	0.7892	-0.05
													Dummy X vs Dummy Z	-0.19	0.3553	-0.18
													Dummy Y vs Dummy Z	-0.07	0.7310	-0.06
CAPSW-SEVERITY SUBTOTAL G	58	7.74	-2.89	48	7.67	-2.35	59	7.83	-1.91	59	7.39	-1.85	Dummy W vs Dummy Z	-1.04	0.0159	-0.45
													Dummy W vs Dummy Y	-0.98	0.0231	-0.42
													Dummy W vs Dummy X	-0.54	0.2406	-0.23
													Dummy X vs Dummy Z	-0.50	0.2694	-0.22
													Dummy Y vs Dummy Z	-0.06	0.8895	-0.03
CAPSW-GLOBAL VALIDITY	58	0.17	0.02	48	0.19	0.00	59	0.17	-0.10	59	0.08	0.00	Dummy W vs Dummy Z	0.02	0.7128	0.07
													Dummy W vs Dummy Y	0.13	0.0219	0.43
													Dummy W vs Dummy X	0.02	0.7506	0.06
													Dummy X vs Dummy Z	0.00	0.9796	0.00
													Dummy Y vs Dummy Z	-0.11	0.0510	-0.36

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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Adjusted Mean Change [REDACTED] STAT1-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

CAPS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹		P-VALUE ¹		
CAPSW-GLOBAL SEVERITY	58	2.72	-0.98	48	2.77	-0.92	59	2.71	-0.60	59	2.58	-0.72	Dummy W vs Dummy Z	-0.26	0.1195	-0.29
													Dummy W vs Dummy Y	-0.38	0.0232	-0.42
													Dummy W vs Dummy X	-0.07	0.7127	-0.07
													Dummy X vs Dummy Z	-0.19	0.2749	-0.21
													Dummy Y vs Dummy Z	0.12	0.4699	0.13
CAPSW-GLOBAL IMPROVEMENT	58	3.69	-1.43	48	3.65	-1.20	59	3.63	-0.83	59	3.59	-1.11	Dummy W vs Dummy Z	-0.32	0.1267	-0.28
													Dummy W vs Dummy Y	-0.60	0.0047	-0.53
													Dummy W vs Dummy X	-0.23	0.2943	-0.21
													Dummy X vs Dummy Z	-0.08	0.7055	-0.07
													Dummy Y vs Dummy Z	0.28	0.1769	0.25
CAPSW-DEPERSONA LIZATION SEVERITY	58	0.26	-0.30	48	0.38	-0.11	59	0.29	-0.24	59	0.25	-0.21	Dummy W vs Dummy Z	-0.09	0.2168	-0.23
													Dummy W vs Dummy Y	-0.06	0.4517	-0.14
													Dummy W vs Dummy X	-0.19	0.0198	-0.46
													Dummy X vs Dummy Z	0.10	0.2279	0.24
													Dummy Y vs Dummy Z	-0.04	0.6303	-0.09

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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Adjusted Mean Change [REDACTED] STAT1-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

CAPS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹		P-VALUE ¹		
CAPSW-DEREALIZA TION SEVERITY	58	0.28	-0.29	48	0.42	-0.13	59	0.27	-0.19	59	0.31	-0.27	Dummy W vs Dummy Z	-0.03	0.7676	-0.05
													Dummy W vs Dummy Y	-0.10	0.2441	-0.22
													Dummy W vs Dummy X	-0.16	0.0864	-0.34
													Dummy X vs Dummy Z	0.14	0.1476	0.28
													Dummy Y vs Dummy Z	0.08	0.3828	0.16
CAPSW-SEVERITY SUBTOTAL DISS	58	0.53	-0.59	48	0.79	-0.24	59	0.56	-0.43	59	0.56	-0.47	Dummy W vs Dummy Z	-0.12	0.3825	-0.16
													Dummy W vs Dummy Y	-0.16	0.2534	-0.21
													Dummy W vs Dummy X	-0.35	0.0187	-0.46
													Dummy X vs Dummy Z	0.23	0.1170	0.31
													Dummy Y vs Dummy Z	0.04	0.7818	0.05
CAPS-5 SUBSCALE B TOTAL SEVERITY SCORE	58	9.59	-5.27	48	9.85	-4.27	59	10.00	-2.87	59	9.83	-4.12	Dummy W vs Dummy Z	-1.15	0.1829	-0.25
													Dummy W vs Dummy Y	-2.39	0.0062	-0.51
													Dummy W vs Dummy X	-0.99	0.2811	-0.21
													Dummy X vs Dummy Z	-0.15	0.8654	-0.03
													Dummy Y vs Dummy Z	1.24	0.1470	0.27

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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Adjusted Mean Change [REDACTED] STAT1-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

CAPS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹		P-VALUE ¹		
CAPS-5 SUBSCALE C TOTAL SEVERITY SCORE	58	5.02	-2.19	48	5.06	-1.72	59	5.08	-1.35	59	5.03	-1.81	Dummy W vs Dummy Z	-0.38	0.3588	-0.17
													Dummy W vs Dummy Y	-0.84	0.0413	-0.38
													Dummy W vs Dummy X	-0.47	0.2858	-0.21
													Dummy X vs Dummy Z	0.09	0.8303	0.04
													Dummy Y vs Dummy Z	0.46	0.2532	0.21
CAPS-5 SUBSCALE D TOTAL SEVERITY SCORE	58	14.95	-6.66	48	14.63	-4.73	59	14.86	-4.45	59	13.69	-4.30	Dummy W vs Dummy Z	-2.36	0.0153	-0.45
													Dummy W vs Dummy Y	-2.21	0.0225	-0.43
													Dummy W vs Dummy X	-1.93	0.0615	-0.37
													Dummy X vs Dummy Z	-0.43	0.6713	-0.08
													Dummy Y vs Dummy Z	-0.15	0.8750	-0.03
CAPS-5 SUBSCALE E TOTAL SEVERITY SCORE	58	10.90	-3.53	48	11.35	-2.99	59	10.58	-2.90	59	11.29	-2.75	Dummy W vs Dummy Z	-0.78	0.2361	-0.22
													Dummy W vs Dummy Y	-0.64	0.3395	-0.18

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Adjusted Mean Change [REDACTED] STAT1-1.1 in CAPS-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

CAPS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
CAPS-5 SUBSCALE E TOTAL SEVERITY SCORE													Dummy W vs Dummy X	-0.55	0.4393	-0.15
													Dummy X vs Dummy Z	-0.23	0.7380	-0.07
													Dummy Y vs Dummy Z	-0.15	0.8225	-0.04
CAPS-5 TOTAL SEVERITY SCORE	58	40.45	-17.7	48	40.90	-14.0	59	40.53	-11.6	59	39.85	-13.0	Dummy W vs Dummy Z	-4.77	0.0389	-0.38
													Dummy W vs Dummy Y	-6.10	0.0087	-0.49
													Dummy W vs Dummy X	-3.73	0.1283	-0.30
													Dummy X vs Dummy Z	-1.03	0.6703	-0.08
													Dummy Y vs Dummy Z	1.33	0.5595	0.11

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BREXPIRAZOLE
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STAT1-1.2
 Adjusted Mean Change from Baeline (Day 0) in SOTS Line Items at Week 12 - MMRM
 (Modified Intent to Treat Sample)

SOTS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹		P-VALUE ¹		
SOTS-RE-EXPERIE NCING	55	4.73	-2.09	47	4.68	-1.31	57	4.75	-1.71	57	4.42	-1.65	Dummy W vs Dummy Z	-0.43	0.1892	-0.25
													Dummy W vs Dummy Y	-0.38	0.2455	-0.22
													Dummy W vs Dummy X	-0.78	0.0279	-0.44
													Dummy X vs Dummy Z	0.35	0.3234	0.20
													Dummy Y vs Dummy Z	-0.05	0.8737	-0.03
SOTS-HYPERAROUS AL	55	4.60	-0.86	47	4.60	-1.14	57	4.70	-1.69	57	4.49	-0.88	Dummy W vs Dummy Z	0.03	0.9268	0.02
													Dummy W vs Dummy Y	0.83	0.0055	0.53
													Dummy W vs Dummy X	0.28	0.3744	0.18
													Dummy X vs Dummy Z	-0.26	0.4200	-0.16
													Dummy Y vs Dummy Z	-0.80	0.0069	-0.51
SOTS-AFFECTIVE DYSREGULATION	55	3.55	-1.39	47	3.70	-1.39	57	3.81	-1.78	57	3.33	-1.44	Dummy W vs Dummy Z	0.04	0.8862	0.03
													Dummy W vs Dummy Y	0.38	0.2082	0.24
													Dummy W vs Dummy X	-0.00	0.9987	-0.00
													Dummy X vs Dummy Z	0.04	0.8923	0.03
													Dummy Y vs Dummy Z	-0.34	0.2609	-0.21
SOTS-IMPULSIVIT Y	55	1.91	-0.34	47	1.53	-0.39	57	2.04	-0.57	57	2.04	-0.52	Dummy W vs Dummy Z	0.18	0.3813	0.17

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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STAT1-1.2
 Adjusted Mean Change from Baeline (Day 0) in SOTS Line Items at Week 12 - MMRM
 (Modified Intent to Treat Sample)

SOTS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹		P-VALUE ¹		
SOTS-IMPULSIVIT Y													Dummy W vs Dummy Y	0.23	0.2630	0.21
													Dummy W vs Dummy X	0.05	0.8173	0.05
													Dummy X vs Dummy Z	0.13	0.5607	0.11
													Dummy Y vs Dummy Z	-0.05	0.8030	-0.05
SOTS-AVOIDANCE	55	4.95	-1.55	47	4.81	-1.19	57	5.07	-1.35	57	4.75	-1.27	Dummy W vs Dummy Z	-0.29	0.3750	-0.17
													Dummy W vs Dummy Y	-0.21	0.5260	-0.12
													Dummy W vs Dummy X	-0.36	0.2998	-0.21
													Dummy X vs Dummy Z	0.07	0.8307	0.04
													Dummy Y vs Dummy Z	-0.08	0.7993	-0.05
SOTS-NUMBING	55	3.04	-1.09	47	3.11	-0.81	57	3.14	-1.06	57	3.21	-1.07	Dummy W vs Dummy Z	-0.02	0.9531	-0.01
													Dummy W vs Dummy Y	-0.03	0.9101	-0.02
													Dummy W vs Dummy X	-0.29	0.3766	-0.18
													Dummy X vs Dummy Z	0.27	0.4036	0.16
													Dummy Y vs Dummy Z	0.02	0.9565	0.01
SOTS-ATTENTIN CONSCIOUSNESS DISSOCIATION	55	1.98	-0.74	47	2.32	-0.65	57	1.79	-0.59	57	1.95	-0.45	Dummy W vs Dummy Z	-0.29	0.1586	-0.27
													Dummy W vs Dummy Y	-0.15	0.4552	-0.14
													Dummy W vs Dummy X	-0.09	0.6848	-0.08

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STAT1-1.2
 Adjusted Mean Change from Baeline (Day 0) in SOTS Line Items at Week 12 - MMRM
 (Modified Intent to Treat Sample)

SOTS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹		P-VALUE ¹		
SOTS-ATTENTIN CONSCIOUSNESS DISSOCIATION													Dummy X vs Dummy Z	-0.20	0.3665	-0.18
													Dummy Y vs Dummy Z	-0.14	0.5042	-0.13
SOTS-SELF PERCEPTION	55	3.93	-1.52	47	4.06	-1.51	57	4.28	-1.43	57	3.96	-1.59	Dummy W vs Dummy Z	0.07	0.8195	0.04
													Dummy W vs Dummy Y	-0.09	0.7575	-0.06
													Dummy W vs Dummy X	-0.01	0.9742	-0.01
													Dummy X vs Dummy Z	0.08	0.8057	0.05
													Dummy Y vs Dummy Z	0.16	0.5887	0.10
SOTS-INTERPERSO NAL RELATION	55	4.80	-1.40	47	4.64	-1.28	57	4.88	-1.85	57	4.68	-0.98	Dummy W vs Dummy Z	-0.42	0.1966	-0.25
													Dummy W vs Dummy Y	0.45	0.1587	0.27
													Dummy W vs Dummy X	-0.11	0.7477	-0.06
													Dummy X vs Dummy Z	-0.30	0.3763	-0.17
													Dummy Y vs Dummy Z	-0.87	0.0070	-0.51
SOTS-ALTERATION S IN SEXUAL RELATIONS	55	2.93	-0.83	47	2.85	-0.72	57	3.07	-0.66	57	2.44	-0.86	Dummy W vs Dummy Z	0.04	0.9137	0.02
													Dummy W vs Dummy Y	-0.16	0.6256	-0.09

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STAT1-1.2
 Adjusted Mean Change from Baeline (Day 0) in SOTS Line Itemsat Week 12 - MMRM
 (Modified Intent to Treat Sample)

SOTS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹		P-VALUE ¹		
SOTS-ALTERATION S IN SEXUAL RELATIONS													Dummy W vs Dummy X	-0.10	0.7719	-0.06
													Dummy X vs Dummy Z	0.14	0.6941	0.08
													Dummy Y vs Dummy Z	0.20	0.5505	0.11
SOTS-SUSTAINING BELIEFS	55	2.76	-1.06	47	2.55	-0.80	57	2.63	-0.79	57	2.79	-0.82	Dummy W vs Dummy Z	-0.23	0.3823	-0.17
													Dummy W vs Dummy Y	-0.27	0.3098	-0.19
													Dummy W vs Dummy X	-0.26	0.3697	-0.18
													Dummy X vs Dummy Z	0.03	0.9297	0.02
													Dummy Y vs Dummy Z	0.04	0.8846	0.03
SOTS-SOMATIC DYSREGULATION	55	1.93	-0.65	47	1.89	-0.59	57	2.00	-0.56	57	1.82	-0.42	Dummy W vs Dummy Z	-0.23	0.2666	-0.21
													Dummy W vs Dummy Y	-0.09	0.6694	-0.08
													Dummy W vs Dummy X	-0.05	0.8096	-0.05
													Dummy X vs Dummy Z	-0.17	0.4276	-0.16
													Dummy Y vs Dummy Z	-0.14	0.4932	-0.13
SOTS TOTAL SCORE	55	41.09	-13.5	47	40.74	-11.9	57	42.16	-13.9	57	39.89	-12.1	Dummy W vs Dummy Z	-1.42	0.4763	-0.13
													Dummy W vs Dummy Y	0.40	0.8424	0.04

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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 OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIRAZOLE STAT1-1.2 FINAL

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STAT1-1.2
 Adjusted Mean Change from Baeline (Day 0) in SOTS Line Itemsat Week 12 - MMRM
 (Modified Intent to Treat Sample)

SOTS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹	N	Base	Change ¹		P-VALUE ¹		
SOTS TOTAL SCORE													Dummy W vs Dummy X	-1.63	0.4452	-0.15
													Dummy X vs Dummy Z	0.22	0.9189	0.02
													Dummy Y vs Dummy Z	-1.81	0.3613	-0.17

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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Adjusted Mean Change [REDACTED] STAT1-1.3 in PCL-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

PCL5 Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
PCL5-REP DISTRB UNWNTD MEMRS STRESS EXP	58	2.55	-1.15	48	2.56	-0.80	59	2.71	-0.81	59	2.32	-0.86	Dummy W vs Dummy Z	-0.29	0.1536	-0.26
													Dummy W vs Dummy Y	-0.34	0.0967	-0.31
													Dummy W vs Dummy X	-0.35	0.1028	-0.32
													Dummy X vs Dummy Z	0.06	0.7681	0.06
													Dummy Y vs Dummy Z	0.05	0.8076	0.04
PCL5-REP DISTRB DREAMS STRESS EXP	58	1.84	-0.85	48	2.48	-0.70	59	2.39	-0.62	59	2.05	-0.63	Dummy W vs Dummy Z	-0.22	0.3157	-0.19
													Dummy W vs Dummy Y	-0.24	0.2895	-0.20
													Dummy W vs Dummy X	-0.16	0.5066	-0.13
													Dummy X vs Dummy Z	-0.06	0.7913	-0.05
													Dummy Y vs Dummy Z	0.02	0.9412	0.01
PCL5-SUDDN FEELNG STRES EXP HAPPN AGAIN	58	1.69	-0.66	48	2.02	-0.70	59	1.81	-0.51	59	1.51	-0.85	Dummy W vs Dummy Z	0.19	0.3648	0.17
													Dummy W vs Dummy Y	-0.16	0.4560	-0.14
													Dummy W vs Dummy X	0.04	0.8723	0.03
													Dummy X vs Dummy Z	0.15	0.4945	0.13

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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Adjusted Mean Change [REDACTED] STAT1-1.3 in PCL-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

PCL5 Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
PCL5-SUDDN FEELNG STRES EXP HAPPN AGAIN													Dummy Y vs Dummy Z	0.34	0.0989	0.31
PCL5-FEEL UPST SMTHNG REMNDS STRESS EXP	58	2.76	-0.98	48	2.81	-0.76	59	2.78	-0.65	59	2.61	-0.65	Dummy W vs Dummy Z	-0.33	0.1202	-0.29
													Dummy W vs Dummy Y	-0.33	0.1257	-0.28
													Dummy W vs Dummy X	-0.22	0.3359	-0.19
													Dummy X vs Dummy Z	-0.11	0.6167	-0.10
													Dummy Y vs Dummy Z	-0.00	0.9858	-0.00
PCL5-HAVNG STRNG PHY REACTNS STRESS EXP	58	2.55	-1.00	48	2.54	-0.84	59	2.66	-0.57	59	2.56	-0.68	Dummy W vs Dummy Z	-0.32	0.1375	-0.28
													Dummy W vs Dummy Y	-0.43	0.0433	-0.38
													Dummy W vs Dummy X	-0.16	0.4821	-0.14
													Dummy X vs Dummy Z	-0.16	0.4858	-0.14
													Dummy Y vs Dummy Z	0.12	0.5801	0.10

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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Adjusted Mean Change [REDACTED] STAT1-1.3 in PCL-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

PCL5 Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
PCL5-AVOID MEMRS THOUGHTS FEEL STRES EXP	58	2.69	-0.91	48	2.81	-0.61	59	2.71	-0.48	59	2.90	-0.64	Dummy W vs Dummy Z	-0.27	0.2754	-0.20
													Dummy W vs Dummy Y	-0.43	0.0798	-0.33
													Dummy W vs Dummy X	-0.30	0.2531	-0.22
													Dummy X vs Dummy Z	0.03	0.9040	0.02
													Dummy Y vs Dummy Z	0.16	0.5035	0.12
PCL5-AVOID EXTRNL REMINDRS STRESS EXP	58	2.62	-0.75	48	2.81	-0.71	59	2.88	-0.57	59	2.71	-0.59	Dummy W vs Dummy Z	-0.16	0.5076	-0.12
													Dummy W vs Dummy Y	-0.18	0.4658	-0.14
													Dummy W vs Dummy X	-0.04	0.8755	-0.03
													Dummy X vs Dummy Z	-0.12	0.6401	-0.09
													Dummy Y vs Dummy Z	0.02	0.9425	0.01
PCL5-TROUBLE REMBRNG IMP PRTS STRES EXP	58	1.38	-0.57	48	1.54	-0.23	59	1.39	-0.64	59	1.29	-0.31	Dummy W vs Dummy Z	-0.26	0.1816	-0.25
													Dummy W vs Dummy Y	0.07	0.7189	0.07
													Dummy W vs Dummy X	-0.35	0.0942	-0.33
													Dummy X vs Dummy Z	0.09	0.6678	0.08

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Adjusted Mean Change [REDACTED] STAT1-1.3 in PCL-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

PCL5 Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹		P-VALUE ¹		
PCL5-TROUBLE REMBRNG IMP PRTS STRES EXP													Dummy Y vs Dummy Z	-0.33	0.0890	-0.31
PCL5-HAVG STRNG NEG BELFS SELF PPL WRLD	58	2.40	-1.28	48	2.42	-0.73	59	2.44	-0.86	59	2.32	-0.56	Dummy W vs Dummy Z	-0.72	0.0012	-0.61
													Dummy W vs Dummy Y	-0.43	0.0556	-0.36
													Dummy W vs Dummy X	-0.55	0.0203	-0.46
													Dummy X vs Dummy Z	-0.17	0.4658	-0.14
													Dummy Y vs Dummy Z	-0.30	0.1771	-0.25
PCL5-BLAMNG SELF OTHRS FOR STRESSFL EXP	58	2.22	-0.85	48	2.35	-0.67	59	2.42	-0.87	59	2.41	-0.77	Dummy W vs Dummy Z	-0.08	0.7350	-0.06
													Dummy W vs Dummy Y	0.01	0.9622	0.01
													Dummy W vs Dummy X	-0.19	0.4663	-0.14
													Dummy X vs Dummy Z	0.11	0.6776	0.08
													Dummy Y vs Dummy Z	-0.09	0.6986	-0.07

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Adjusted Mean Change [REDACTED] STAT1-1.3 in PCL-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

PCL5 Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
PCL5-HAVNG STRNG NEG FEELNGS	58	2.64	-0.97	48	2.75	-0.72	59	2.68	-0.86	59	2.51	-0.64	Dummy W vs Dummy Z	-0.33	0.1509	-0.27
													Dummy W vs Dummy Y	-0.11	0.6430	-0.09
													Dummy W vs Dummy X	-0.25	0.3024	-0.20
													Dummy X vs Dummy Z	-0.08	0.7520	-0.06
													Dummy Y vs Dummy Z	-0.22	0.3285	-0.18
PCL5-LOSS INTRST ACTIVITIES USD TO ENJOY	58	2.76	-1.26	48	2.75	-0.68	59	2.66	-0.54	59	2.39	-0.77	Dummy W vs Dummy Z	-0.49	0.0346	-0.39
													Dummy W vs Dummy Y	-0.72	0.0018	-0.59
													Dummy W vs Dummy X	-0.58	0.0187	-0.46
													Dummy X vs Dummy Z	0.09	0.7127	0.07
													Dummy Y vs Dummy Z	0.24	0.2987	0.19
PCL5-FEELNG DISTANT CUT OFF FROM OTHERS	58	2.71	-1.06	48	2.96	-0.88	59	3.03	-0.75	59	2.66	-0.51	Dummy W vs Dummy Z	-0.55	0.0140	-0.46
													Dummy W vs Dummy Y	-0.31	0.1656	-0.26
													Dummy W vs Dummy X	-0.19	0.4320	-0.15
													Dummy X vs Dummy Z	-0.36	0.1255	-0.30

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Adjusted Mean Change [REDACTED] STAT1-1.3 in PCL-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

PCL5 Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹		P-VALUE ¹		
PCL5-FEELNG DISTANT CUT OFF FROM OTHERS													Dummy Y vs Dummy Z	-0.24	0.2878	-0.20
PCL5-TRBLE EXPERINCNG POSITIVE FEELNGS	58	2.26	-0.94	48	2.50	-0.71	59	2.44	-0.67	59	2.20	-0.79	Dummy W vs Dummy Z	-0.14	0.4800	-0.13
													Dummy W vs Dummy Y	-0.27	0.1980	-0.24
													Dummy W vs Dummy X	-0.23	0.2963	-0.20
													Dummy X vs Dummy Z	0.08	0.6980	0.08
													Dummy Y vs Dummy Z	0.12	0.5541	0.11
PCL5-IRRITBLE BEHAV ANGRY OUTBRST AGRSV	58	2.05	-0.78	48	2.08	-0.60	59	2.05	-0.63	59	1.92	-0.70	Dummy W vs Dummy Z	-0.08	0.7288	-0.06
													Dummy W vs Dummy Y	-0.15	0.5014	-0.12
													Dummy W vs Dummy X	-0.18	0.4535	-0.15
													Dummy X vs Dummy Z	0.10	0.6698	0.08
													Dummy Y vs Dummy Z	0.07	0.7428	0.06

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Adjusted Mean Change [REDACTED] STAT1-1.3 in PCL-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

PCL5 Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
PCL5-TAKNG TOO MNY RISKS THT CAUSE HARM	58	0.86	-0.31	48	0.85	-0.17	59	0.86	-0.52	59	0.78	-0.23	Dummy W vs Dummy Z	-0.08	0.5930	-0.10
													Dummy W vs Dummy Y	0.21	0.1387	0.28
													Dummy W vs Dummy X	-0.14	0.3695	-0.18
													Dummy X vs Dummy Z	0.06	0.6896	0.08
													Dummy Y vs Dummy Z	-0.29	0.0433	-0.37
PCL5-BEING SUPERALERT WATCHFUL ON GUARD	58	2.90	-0.78	48	2.98	-0.64	59	2.71	-0.76	59	2.93	-0.71	Dummy W vs Dummy Z	-0.07	0.7687	-0.05
													Dummy W vs Dummy Y	-0.02	0.9356	-0.01
													Dummy W vs Dummy X	-0.13	0.5937	-0.10
													Dummy X vs Dummy Z	0.06	0.7939	0.05
													Dummy Y vs Dummy Z	-0.05	0.8313	-0.04
PCL5-FEELING JUMPY OR EASILY STARTLED	58	2.26	-0.68	48	2.42	-0.55	59	2.17	-0.53	59	2.56	-0.78	Dummy W vs Dummy Z	0.10	0.6532	0.08
													Dummy W vs Dummy Y	-0.15	0.5099	-0.12
													Dummy W vs Dummy X	-0.13	0.6037	-0.10
													Dummy X vs Dummy Z	0.23	0.3416	0.19

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Adjusted Mean Change [REDACTED] STAT1-1.3 in PCL-5 Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

PCL5 Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹				
PCL5-FEELING JUMPY OR EASILY STARTLED													Dummy Y vs Dummy Z	0.25	0.2685	0.20
PCL5-HAVNG DIFFICULTY CONCENTRATNG	58	2.81	-0.93	48	2.96	-0.62	59	2.61	-0.63	59	2.56	-0.63	Dummy W vs Dummy Z	-0.30	0.1386	-0.28
													Dummy W vs Dummy Y	-0.30	0.1351	-0.28
													Dummy W vs Dummy X	-0.31	0.1444	-0.29
													Dummy X vs Dummy Z	0.02	0.9416	0.01
													Dummy Y vs Dummy Z	0.00	0.9841	0.00
PCL5-TROUBLE FALLING OR STAYING ASLEEP	58	2.52	-0.83	48	3.10	-0.73	59	2.85	-0.43	59	3.02	-0.65	Dummy W vs Dummy Z	-0.18	0.4323	-0.15
													Dummy W vs Dummy Y	-0.40	0.0773	-0.33
													Dummy W vs Dummy X	-0.10	0.6735	-0.08
													Dummy X vs Dummy Z	-0.08	0.7458	-0.06
													Dummy Y vs Dummy Z	0.22	0.3244	0.18
PCL-5 TOTAL SCORE	58	46.47	-17.4	48	49.71	-13.5	59	48.27	-13.1	59	46.20	-12.9	Dummy W vs Dummy Z	-4.50	0.1157	-0.29
													Dummy W vs Dummy Y	-4.26	0.1387	-0.27

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Adjusted Mean Change [REDACTED] STAT1-1.3 in PCL-5 Line Items [REDACTED] - MMRM
(Modified Intent to Treat Sample)

PCL5 Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹	N	Base	LSMean Change ¹		P-VALUE ¹		
PCL-5 TOTAL SCORE													Dummy W vs Dummy X	-3.85	0.2081	-0.25
													Dummy X vs Dummy Z	-0.65	0.8305	-0.04
													Dummy Y vs Dummy Z	-0.24	0.9339	-0.02

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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OPDC, NEW DRUG APPLICATION, IND # 115960 BREXPIPIRAZOLE STAT1-1.3 FINAL

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BREXPIRAZOLE
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1 OF 6

Adjusted Mean Change [REDACTED] STAT1-1.4 in HADS Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

HADS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹		P-VALUE ¹		
HADS01-I FEEL TENSE OR WOUND UP	58	2.05	-0.68	48	2.10	-0.21	59	2.10	-0.38	59	2.07	-0.48	Dummy W vs Dummy Z	-0.19	0.2562	-0.21
													Dummy W vs Dummy Y	-0.30	0.0801	-0.33
													Dummy W vs Dummy X	-0.46	0.0110	-0.50
													Dummy X vs Dummy Z	0.27	0.1317	0.29
													Dummy Y vs Dummy Z	0.11	0.5285	0.12
HADS01-ENJOY THE THINGS I USED TO ENJOY	58	1.91	-0.64	48	1.81	-0.48	59	1.75	-0.24	59	1.66	-0.61	Dummy W vs Dummy Z	-0.03	0.8592	-0.03
													Dummy W vs Dummy Y	-0.40	0.0330	-0.40
													Dummy W vs Dummy X	-0.17	0.4026	-0.16
													Dummy X vs Dummy Z	0.13	0.4989	0.13
													Dummy Y vs Dummy Z	0.37	0.0482	0.37
HADS01-SOMETHIN G AWFUL ABOUT TO HAPPEN	58	2.07	-0.71	48	2.02	-0.32	59	2.02	-0.35	59	2.12	-0.58	Dummy W vs Dummy Z	-0.13	0.4478	-0.14
													Dummy W vs Dummy Y	-0.36	0.0389	-0.38
													Dummy W vs Dummy X	-0.40	0.0320	-0.42
													Dummy X vs Dummy Z	0.27	0.1474	0.28
													Dummy Y vs Dummy Z	0.23	0.1863	0.24

¹ MIXED MODEL REPEATED MEASURES METHOD WITH MODEL TERMS: TREATMENT, STUDY CENTER, VISIT, TREATMENT BY VISIT AND BASELINE BY VISIT INTERACTION.

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Adjusted Mean Change [REDACTED] STAT1-1.4 in HADS Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

HADS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹			P-VALUE ¹	
HADS01-I CAN LAUGH AND SEE FUNNY SIDE	58	1.17	-0.48	48	1.25	-0.06	59	1.10	-0.17	59	1.07	-0.38	Dummy W vs Dummy Z	-0.10	0.5012	-0.12
													Dummy W vs Dummy Y	-0.30	0.0429	-0.38
													Dummy W vs Dummy X	-0.42	0.0089	-0.52
													Dummy X vs Dummy Z	0.32	0.0446	0.39
													Dummy Y vs Dummy Z	0.20	0.1706	0.25
HADS01-WORRYING THOUGHTS GO THROUGH MIND	58	2.10	-0.72	48	2.19	-0.25	59	2.19	-0.44	59	2.34	-0.48	Dummy W vs Dummy Z	-0.23	0.1873	-0.24
													Dummy W vs Dummy Y	-0.28	0.1089	-0.30
													Dummy W vs Dummy X	-0.47	0.0134	-0.49
													Dummy X vs Dummy Z	0.23	0.2117	0.24
													Dummy Y vs Dummy Z	0.05	0.7808	0.05
HADS01-I FEEL CHEERFUL	58	1.64	-0.69	48	1.46	-0.26	59	1.53	-0.41	59	1.34	-0.40	Dummy W vs Dummy Z	-0.29	0.0588	-0.35
													Dummy W vs Dummy Y	-0.28	0.0628	-0.35
													Dummy W vs Dummy X	-0.42	0.0082	-0.52
													Dummy X vs Dummy Z	0.14	0.3819	0.17
													Dummy Y vs Dummy Z	-0.01	0.9633	-0.01

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Adjusted Mean Change [REDACTED] STAT1-1.4 in HADS Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

HADS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN'S D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹				
HADS01-SIT AT EASE AND FEEL RELAXED	58	1.91	-0.46	48	1.90	-0.23	59	1.85	-0.22	59	1.85	-0.39	Dummy W vs Dummy Z	-0.07	0.5957	-0.10
													Dummy W vs Dummy Y	-0.24	0.0883	-0.32
													Dummy W vs Dummy X	-0.23	0.1191	-0.31
													Dummy X vs Dummy Z	0.16	0.2836	0.21
													Dummy Y vs Dummy Z	0.17	0.2342	0.22
HADS01-I FEEL AS IF I AM SLOWED DOWN	58	1.66	-0.57	48	1.65	-0.14	59	1.58	-0.31	59	1.54	-0.49	Dummy W vs Dummy Z	-0.07	0.6584	-0.08
													Dummy W vs Dummy Y	-0.26	0.1263	-0.28
													Dummy W vs Dummy X	-0.43	0.0160	-0.47
													Dummy X vs Dummy Z	0.36	0.0435	0.40
													Dummy Y vs Dummy Z	0.18	0.2706	0.20
HADS01-BUTTERFL IES IN THE STOMACH	58	1.48	-0.42	48	1.48	-0.08	59	1.51	-0.32	59	1.51	-0.49	Dummy W vs Dummy Z	0.07	0.6617	0.08
													Dummy W vs Dummy Y	-0.10	0.4935	-0.13
													Dummy W vs Dummy X	-0.34	0.0335	-0.42
													Dummy X vs Dummy Z	0.41	0.0110	0.50
													Dummy Y vs Dummy Z	0.17	0.2603	0.21

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Adjusted Mean Change [REDACTED] STAT1-1.4 in HADS Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

HADS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹	P-VALUE ¹	COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹				
HADS01-LOST INTEREST IN MY APPEARANCE	58	1.48	-0.36	48	1.29	-0.22	59	1.56	-0.13	59	1.51	-0.31	Dummy W vs Dummy Z	-0.05	0.7444	-0.06
													Dummy W vs Dummy Y	-0.23	0.1493	-0.27
													Dummy W vs Dummy X	-0.14	0.3883	-0.17
													Dummy X vs Dummy Z	0.09	0.5755	0.11
													Dummy Y vs Dummy Z	0.17	0.2602	0.21
HADS01-FEEL RESTLESS BE ON THE MOVE	58	1.93	-0.57	48	1.77	-0.18	59	1.90	-0.42	59	1.97	-0.43	Dummy W vs Dummy Z	-0.14	0.3910	-0.16
													Dummy W vs Dummy Y	-0.15	0.3593	-0.17
													Dummy W vs Dummy X	-0.39	0.0284	-0.43
													Dummy X vs Dummy Z	0.25	0.1603	0.27
													Dummy Y vs Dummy Z	0.01	0.9510	0.01
HADS01-LOOK FORWARD WITH ENJOYMENT	58	1.72	-0.56	48	1.69	-0.15	59	1.73	-0.27	59	1.37	-0.34	Dummy W vs Dummy Z	-0.22	0.2343	-0.22
													Dummy W vs Dummy Y	-0.29	0.1161	-0.29
													Dummy W vs Dummy X	-0.41	0.0361	-0.41
													Dummy X vs Dummy Z	0.19	0.3293	0.19
													Dummy Y vs Dummy Z	0.07	0.7102	0.07

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Adjusted Mean Change [REDACTED] STAT1-1.4 in HADS Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

HADS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN'S D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹			P-VALUE ¹	
HADS01-I GET SUDDEN FEELINGS OF PANIC	58	1.78	-0.41	48	1.83	-0.21	59	1.81	-0.40	59	1.78	-0.38	Dummy W vs Dummy Z	-0.03	0.8607	-0.03
													Dummy W vs Dummy Y	-0.01	0.9567	-0.01
													Dummy W vs Dummy X	-0.20	0.2368	-0.23
													Dummy X vs Dummy Z	0.17	0.3040	0.20
													Dummy Y vs Dummy Z	-0.02	0.9035	-0.02
HADS01-ENJOY GOOD BOOK	58	1.60	-0.46	48	1.33	-0.13	59	1.20	-0.23	59	1.10	-0.27	Dummy W vs Dummy Z	-0.19	0.2252	-0.22
													Dummy W vs Dummy Y	-0.23	0.1421	-0.27
													Dummy W vs Dummy X	-0.33	0.0467	-0.39
													Dummy X vs Dummy Z	0.14	0.3916	0.17
													Dummy Y vs Dummy Z	0.04	0.7984	0.05
HADS SUBSCALE A TOTAL SCORE	58	13.33	-3.98	48	13.29	-1.54	59	13.37	-2.55	59	13.63	-3.33	Dummy W vs Dummy Z	-0.66	0.4175	-0.15
													Dummy W vs Dummy Y	-1.44	0.0791	-0.33
													Dummy W vs Dummy X	-2.44	0.0051	-0.55
													Dummy X vs Dummy Z	1.78	0.0384	0.41
													Dummy Y vs Dummy Z	0.78	0.3368	0.18

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6 OF 6

Adjusted Mean Change [REDACTED] STAT1-1.4 in HADS Line Items [REDACTED] - MMRM
 (Modified Intent to Treat Sample)

HADS Line Items	BREX+SERT			BREX			SERT			PLACEBO			TREATMENT COMPARISON	ESTIMATED TREATMENT EFFECT ¹		COHEN's D EFFECT SIZE
	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹	N	MEAN Base	LSMean Change ¹			P-VALUE ¹	
HADS SUBSCALE	58	11.19	-3.91	48	10.48	-1.53	59	10.44	-1.83	59	9.59	-2.61	Dummy W vs Dummy Z	-1.31	0.0946	-0.31
D TOTAL SCORE													Dummy W vs Dummy Y	-2.08	0.0078	-0.50
													Dummy W vs Dummy X	-2.39	0.0041	-0.57
													Dummy X vs Dummy Z	1.08	0.1857	0.26
													Dummy Y vs Dummy Z	0.78	0.3127	0.19

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