16.1.9 Documentation of Statistical Codes

Statistical Analysis Plan

Sponsor:	BioDelivery Sciences International, Inc.
Protocol No:	BUP-401
Protocol Title:	A RANDOMIZED, DOUBLE-BLIND, DOUBLE-DUMMY, 6-PERIOD, PLACEBO-CONTROLLED, CROSSOVER STUDY TO EXPLORE AND COMPARE THE VENTILATORY RESPONSE TO HYPERCAPNIA (VRH), OF BELBUCA, OXYCODONE HYDROCHLORIDE, AND PLACEBO IN RECREATIONAL OPIOID USERS
PRA Project ID:	BDL673SL-186739
Version Date:	07-Oct-2019 (SAP)

1.0 Approvals

The undersigned have approved this Statistical Analysis Plan for use in this study.

Name of Sponsor Representative / Title:	[redacted]
Signature of Sponsor Representative / Date:	[redacted]
Name of Author / Title:	[redacted]
Signature of Author / Date:	

2.0 Table of Contents

3.0 Introduction

This Statistical Analysis Plan (SAP) describes the statistical methods that will be used during the analysis and reporting of data collected under BioDelivery Sciences International, Inc. Protocol BUP-401.

This SAP should be read in conjunction with the study protocol and electronic case report form (eCRF). This version of the plan has been developed using the protocol dated 24-May-201912 (including all amendments up to this protocol date) and the final eCRF(s) dated 24-Aug-2019.

An approved and signed SAP is a requirement for database lock. An approved SAP is also required for unblinding of the study treatments.

This SAP only covers the results that will be processed by the PRA Early Development Services (EDS) Biostatistics Department.

PRA EDS will perform the pharmacokinetic (PK), pharmacodynamic (PD), and safety and tolerability evaluation.

This SAP supersedes the statistical considerations identified in the protocol; where considerations are substantially different, they will be so identified. Any post-hoc or unplanned analyses, or significant changes from the planned analysis in this SAP performed to provide results for inclusion in the clinical study report (CSR) but not included in this SAP, will be clearly identified in the CSR. Changes to planned analyses do not require an updated SAP but should be included in the CSR if significant.

4.0 Changes from Previous Version of Approved SAP

This is the first version of the SAP.

5.0 Study Objectives

5.1 Primary

- Respiratory drive will be evaluated by measuring the ventilatory response to hypercapnia (VRH) by maximum decrease in minute ventilation after administration of Belbuca, oxycodone hydrochloride, and placebo.

5.1.1 Primary Endpoints

- Ventilatory response to hypercapnia
  - Minute ventilation (expired minute volume, V_E; L/min)
  - Respiratory rate (breaths/min)
  - Flow rates (peak expired flow, PEF; L/min)
  - Tidal volume (expired tidal volume, V_T; mL)
  - End-tidal CO_2 (ET_{CO2}, mmHg)
  - Hypercapnic Ventilatory Response, expressed in L/min per mm Hg
  - Ratio of V_E / ET_{CO2}, expressed in L/min per mm Hg

5.2 Secondary

- Pupil diameter will be assessed by pupillometry predose and at multiple timepoints after completion of Belbuca, oxycodone hydrochloride, and placebo dosing.
- Change in ratio of minute ventilation over end-tidal CO2 predose and at multiple timepoints after oral administration of Belbuca, oxycodone hydrochloride, and placebo.

- Clinical safety data from adverse event (AE) reporting, clinical observations, 12-lead electrocardiograms (ECGs), vital signs (blood pressure [BP], heart rate [HR], respiratory rate, and oral temperature), oxygen saturation, and safety laboratory tests following administration of Belbuca, oxycodone hydrochloride, and placebo will be summarized, and any clinically significant abnormalities will be described.

5.2.1 Secondary Endpoints

- Pupil diameter (for each measurement during pupillometry, a single pupil diameter will be recorded)
- Safety endpoints including:
  - AEs
  - Safety laboratory (hematology, blood chemistry, urinalysis, serology, alcohol breath test, pregnancy & FSH)
  - Vital signs (BP, RR, oral temperature)
  - ECG (HR, PR-interval, QRS-duration, QT-interval, QTc-interval (Fridericia's))
  - Pulse Oximetry (continuous oxygen saturation monitoring of peripheral capillary oxygen saturation (SpO_2))
  - Columbia-Suicide Severity Rating Scale
  - Cardiac Telemetry (continuous measurement during VHR testing)
  - Physical Exam
  - COWS (assessments of opiate withdrawal symptoms during Naloxone Challenge)

5.3 Exploratory

- Blood samples will be collected to evaluate pharmacokinetic (PK) and blood levels of Belbuca and oxycodone hydrochloride at important pharmacodynamic (PD) endpoints.

5.4 Study Hypothesis

Although there is no formal study hypothesis, the rationale for this study is to compare the effects of increasing dose and respiratory depression between a Schedule II opioid (oxycodone hydrochloride) and Schedule III opioid (Belbuca). In this study, the effect of 300 µg, 600 µg, and 900 µg doses of Belbuca (Schedule III), 30 mg and 60 mg of oxycodone hydrochloride (Schedule II), and placebo, on the respiratory drive will be evaluated by measuring the ventilatory response to hypercapnia (VRH).

6.0 Study Design

This is a double-blind, double-dummy, oral/buccal, 6-treatment, 6-period, placebo-controlled, randomized, crossover study with the following treatments (given in the sequences specified in Table 1 below), each separated by an approximate 7-day washout period, in up to 18 male or female subjects self-identifying as recreational drug users. The study will consist of a Screening Phase, a Treatment Phase (which includes the Naloxone Challenge Test), and a Follow-Up Phase.

- Belbuca 300 µg and oral placebo
- Belbuca 600 µg and oral placebo
- Belbuca 900 µg and oral placebo
- Oxycodone 30 mg and buccal placebo
- Oxycodone 60 mg and buccal placebo
- Oral placebo and buccal placebo

Screening Phase

Study-specific screening procedures will include: a physical examination (PE), including measurement of height, weight, and vital signs; blood and urine laboratory testing; review of medical and medication history; and a 12-lead ECG. The subjects will also undergo the VRH procedure to determine tolerability of the procedure and demonstrate adequate VRH.

Treatment Phase

All subjects with a negative urine drug screen on Day -1 will undergo the Naloxone Challenge Test. Subjects will receive an initial dose of naloxone hydrochloride 0.2 mg by intravenous bolus, followed by an assessment of signs of withdrawal. The subject will be assessed by a medical provider for signs or symptoms of withdrawal through assessments of the COWS scores. If no evidence of withdrawal occurs within 30 seconds, an additional 0.6 mg naloxone will be administered by intravenous bolus. A second COWS assessment will be done 5 minutes after the 0.6 mg naloxone dose administration. A COWS score of >5 will result in a failed naloxone challenge. Subject safety will be monitored for 60 minutes after the administration of naloxone.

After completing and passing the Naloxone Challenge Test, subjects will be randomized to 1 of 6 treatment sequences in a 1:1:1:1:1:1 ratio on Day 1. Subjects will receive all six treatments in the order specified by a Williams design sequence where every treatment follows every other treatment at least once (Table 1). Treatment will be double-blind, double-dummy whereby subjects will receive both buccal film (active or placebo) and a capsule (active or placebo).

Table 1 Assignment of Subjects to Treatments

Sequence	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6
1	Treatment C	Treatment A	Treatment D	Treatment B	Treatment F	Treatment E
2	Treatment D	Treatment C	Treatment F	Treatment A	Treatment E	Treatment B
3	Treatment F	Treatment D	Treatment E	Treatment C	Treatment B	Treatment A
4	Treatment E	Treatment F	Treatment B	Treatment D	Treatment A	Treatment C
5	Treatment B	Treatment E	Treatment A	Treatment F	Treatment C	Treatment D
6	Treatment A	Treatment B	Treatment C	Treatment E	Treatment D	Treatment F

Treatment A: Belbuca 300 µg and oral placebo
Treatment B: Belbuca 600 µg and oral placebo
Treatment C: Belbuca 900 µg and oral placebo
Treatment D: Oxycodone 30 mg and buccal placebo
Treatment E: Oxycodone 60 mg and buccal placebo
Treatment F: Oral placebo and buccal placebo

Primary assessments include ventilatory responses to hypercapnia, and secondary assessments include pupillometry and safety measurements.

6.1 Sample Size Considerations

No formal sample size calculation was made. Based on similar studies, the number of subjects is considered appropriate for this Phase 1 study.

6.2 Randomization

Subjects will be randomized to 1 of 6 treatment sequences (Table 1) according to the randomization code generated by the Biostatistics Department of PRA. The subject number will ensure identification throughout the study. Randomization numbers will range from 1001 to 1018. Replacement subjects will receive the number of the subject to be replaced, increased by 1000 (e.g., 2001 replacement number for subject number 1001), and will be administered the same (or remaining) treatments in the same order.

7.0 Overview of Planned Analysis

7.1 Changes from Protocol

There are no changes from the protocol.

7.2 Interim Analysis and Key Results

There will be no interim analyses or summaries of data provided prior to the delivery of the full set of post-lock tables, figures and listings (TFLs).

7.3 Final Analysis

Draft TFLs will be provided after database lock. After Sponsor comments have been incorporated, the TFLs will be finalized and incorporated in the first draft CSR.

8.0 Data Review

8.1 Data Management

Data handling and transfer will take place under the PRA Data Management Plan for the study.

8.2 Acceptance of Data for Summarization

Programming of analysis datasets and TFLs may be ongoing during the data management of the study. However, programming of analysis datasets and TFLs will be completed and quality controlled (QC'd) after database lock. Only quality assured (QA'd) results released by the Safety Laboratory, Bioanalytical Laboratory, or other external data source will be used for the programming of analysis datasets and TFLs for the final report. Any data values requiring investigation or corrections that are identified while programming the analysis datasets and TFLs will be sent to the project Data Manager. If the issue affects the TFLs the Programmer or Statistician who identified the issue will follow it to resolution.

9.0 Definitions and General Analysis Methods

9.1 Analysis Data Presentation

9.1.1 Rounding

In listings all data will be presented with the same precision as the original data. Derived data will be rounded for presentation purposes.

For summaries, the minimum and maximum will be presented to the same number of decimal places as the original data, the mean, median, and quartiles (Q1 and Q3) will be presented to 1 decimal greater than the original data, and the standard deviation (SD) and standard error (SE) to 2 decimals greater than the original data. Frequency percentages and coefficient of variation (%CV) will be presented with 1 decimal.

The above rule can be applied directly to collected data. For derived data rounding will occur prior to summarization so a specific number of decimal places will have to be assumed to apply the above rounding rules for summary statistics.

PK parameters will be rounded in the derived dataset as determined by the pharmacokineticist. Each parameter will have a fixed number of decimals. The pharmacokineticist will follow this rule when deciding the number of decimals for each parameter: no decimal if data for a parameter are generally greater than or equal to 100; 1 decimal if data are generally between 10 and 100; 2 decimals if data are generally between 1 and 10; 3 decimals if data are generally below 1.

PD parameters will be rounded in the derived dataset as guided by the statistician and presented as is in the listings. Each parameter will have a fixed number of decimals. The statistician will use discretion when deciding the number of decimals for each parameter.

P-values are descriptive only as there is no formal hypothesis test. P-values will be reported to four decimal places; p-values less than 0.0001 will be reported as p <0.0001.

9.1.2 Imputation

Unless otherwise noted, data will not be imputed.

9.1.3 Daylight Savings Time Adjustments

This study is not expected to fall over Daylight Savings Time and no adjustments for time change are planned.

9.1.4 Descriptive Statistics

Unless otherwise indicated, continuous variables will be summarized with the following descriptive statistics: n (number of observations), (arithmetic) mean, standard deviation (SD), minimum (min) value, median, and maximum (max) value.

Categorical data will be summarized with frequencies and percentages. Percentages by categories will be based on the number of subjects exposed within a treatment.

For categorical data the categories will be presented in the tables exactly as they appear in the CRF / Database.

9.1.5 Pooling

Summary statistics will be calculated by treatment and timepoint, if applicable.

9.1.6 Unscheduled Measurements

Unscheduled and early termination measurements will be included in the listings. With the exception of unscheduled measurements used for baseline, unscheduled measurements will be excluded from the descriptive statistics and statistical analysis.

9.2 Analysis Data Definitions

9.2.1 Baseline Definition

Unless otherwise stated, baseline for all post-dose evaluations is defined as the last observation recorded before the first study drug administration, predose is defined as the last observation recorded before the first study drug administration in each period. The last observation can be an unscheduled / repeated measurement. If a pre-treatment observation is missing in a given period then the screening value may be used.

9.2.2 Treatment/Subject Grouping

Label	Grouping
Study Drug	Belbuca 300 µg, Belbuca 600 µg, Belbuca 900 µg, Oxycodone 30 mg, Oxycodone 60 mg, oral placebo, buccal placebo
Treatment	Treatment A: Belbuca 300 µg and oral placebo Treatment B: Belbuca 600 µg and oral placebo Treatment C: Belbuca 900 µg and oral placebo Treatment D: Oxycodone 30 mg and buccal placebo Treatment E: Oxycodone 60 mg and buccal placebo Treatment F: Oral placebo and buccal placebo
Dose Level	Belbuca 300 µg, Belbuca 600 µg, Belbuca 900 µg, Oxycodone 30 mg, and Oxycodone 60 mg

9.2.3 Common Variable Derivations

Variable	Data Type	Definition/Calculation
Change from Baseline/Predose	All	Post-dose Observation minus Baseline/Predose Observation
Analysis Study Day (Prior to Dose)	All	Date of Measurement minus Dose Date
Analysis Study Day (Post Dose)	All	Date of Measurement minus Dose Date +1
Period	All	Interval of time during which treatment is constant. Treatment Phase only.
TEAE	ADAE	AE is a TEAE if the AE Date/Time is greater than or equal to the first dose Date/Time

9.2.4 QC

The analysis datasets and the TFLs will be QC'd according to the PRA EDS QC plan.

9.2.4.1 Critical Data

The QC plan requires datasets be classified as critical or non-critical. The datasets considered critical are subject level, pharmacokinetic, pharmacodynamic, and adverse events (ADSL, ADPC, ADPP, ADPD, ADAE). As these are related to the primary objectives these datasets will be double programmed per the QC Plan.

9.2.5 ADaM Datasets and Metadata

The analysis datasets will be generated in accordance with Clinical Data Interchange Standard Consortium (CDISC) Analysis Data Model (ADaM) Version 2.1.

ADaM compliant datasets will be delivered to the sponsor. A define.xml file version 2 with the corresponding metadata will be included. Analysis results metadata are excluded.

9.3 Software

The statistical analysis and reporting will be done using SAS® for Windows™ Version 9.4 or higher (SAS Institute, Inc.).

PK parameter calculations will primarily be done using Phoenix® WinNonlin® version 8.1 or higher (Certara, L.P.). Additional PK computations may be performed in SAS®.

9.4 Statistical Methods

9.4.1 Statistical Outlier Determination

No statistical outlier analysis is planned.

9.4.2 Predetermined Covariates and Prognostic Factors

There are no predetermined covariates or prognostic factors.

9.4.3 Hypothesis Testing

Although no formal hypothesis testing will be done, the pairwise comparisons outlined in section 17.3 will be performed.

9.5 TFL Layout

Report layout will be according to the PRA EDS – ICH E3 compliant – CSR Template. The layout of TFLs will be according to the PRA EDS standards.

Table shells are provided with and approved as part of this SAP. Small changes to shell layout due to the nature of the data may be required after lock at the discretion of the PRA project statistician. Other changes to the shells may be out of scope. The TFLs will be provided as a single document in Adobe PDF format (in Letter format), and as individual files for each table, figure or listing in Rich Text Format (.rtf).

10.0 Analysis Sets

Analyses	Randomized Set	Safety Set	PK Set	Completers	Partial Completers
Disposition Summaries	✓	✓	✓	✓	✓
Baseline Characteristics	✓	✓	✓	✓	✓
Safety Assessments		✓			
PK Concentrations		✓			
PK Parameters			✓		
Primary PD Analysis				✓	✓

10.1 Randomized Set

The Randomized Set will consist of subjects who are assigned a randomization number in the study. This set will be used for disposition summaries. This set will be analyzed as randomized.

10.2 Safety Set

The Safety Set will consist of subjects who receive at least one dose of any study drug in the Treatment Phase. This set will be used for the safety data summaries, baseline characteristic summaries, and PK concentration summaries. This set will be analyzed as treated.

10.3 Pharmacokinetic Set

The PK Set will consist of all subjects who receive at least 1 dose of any study drug during Treatment Phase and have sufficient concentration-time data to calculate at least one of the primary PK parameters (T_{max}, C_{max}, or AUC_{last}). Subjects or individual PK parameters may be excluded at the discretion of the pharmacokineticist (i.e. in the case of a protocol deviation). This set will be used for the PK parameters and will be analyzed as treated.

10.4 Completers Set

The Completer Set will consist of all randomized subjects who complete all 6 treatment periods in the Treatment Phase with a valid VRH V_E E_{max} measurement in each completed treatment period. Subjects with any major protocol deviations may be excluded. This set will be used for all PD analyses and will be analyzed as treated.

10.5 Partial Completers Set

The Partial Completer Set will consist of all randomized subjects who complete at least 2 treatment periods in the Treatment Phase with a valid VRH V_E E_{max} measurement in each completed treatment period. Note that the mixed model used for this analysis (section 16.3) can accommodate subjects who may not complete all 6 treatment periods. Subjects with any major protocol deviations may be excluded. This set will be used for PD sensitivity analyses and will be analyzed as treated.

11.0 Subject Disposition

The number and percentage of subjects randomized, dosed, and members of each analysis set will be presented. The number and percentage of subjects who withdrew from the study prematurely and a breakdown of the corresponding reasons for withdrawal will also be presented.

12.0 Protocol Deviations

Protocol deviations will be collected and entered into the Clinical Trial Management System (CTMS) per clinical monitoring Standard Operating Procedures. Important protocol deviation data will be listed by subject.

13.0 Demographic and Baseline Characteristics

13.1 Demographics

Subject demographics will be summarized overall for each analysis set. The summary will include the subjects' age (years), sex, race, ethnicity, weight (kg), height (cm), and BMI (kg/m^2).

All demographic data as collected during the screening visit will be listed by subject.

13.2 Medical History

Medical history, categorized by preferred term according to MedDRA, will be summarized. The number and percentage of subjects in each preferred term will be displayed.

Medical history will be listed by subject.

13.3 Recreational Drug, Alcohol and Tobacco History

Recreational drug, alcohol and tobacco history will be summarized and listed by subject.

14.0 Concomitant Medications

Concomitant medications, categorized by medication group and subgroup according to WHO Drug Dictionary, will be summarized. The number and percentage of subjects using each medication will be displayed with the number and percentage of subjects using at least one medication within each medication group and subgroup, by treatment.

Concomitant medication will be listed by subject. Medications with an end date prior to the first dose of study drug will be considered prior medications and will be noted in the listing. If a partial date allows a medication to be considered concomitant it will be categorized as such.

15.0 Treatment Compliance and Exposure

The number of subjects receiving each dose of study drug will be summarized by treatment and listed.

16.0 Pharmacokinetic Analyses

16.1 Pharmacokinetic Variables

Concentrations and PK parameters of buprenorphine, nor-buprenorphine, and oxycodone will be collected in plasma, and the set of PK variables are considered exploratory endpoints.

16.2 Plasma Pharmacokinetic Summaries

16.2.1 Plasma Concentrations

Plasma concentrations for buprenorphine, nor-buprenorphine, and oxycodone below the quantifiable limit (BQL) will be set to 0 in the computation of mean concentration values. Descriptive statistics (number of subjects, arithmetic mean, geometric mean, SD, coefficient of variation, median, min, and max) will be used to summarize the plasma concentrations by treatment at each scheduled timepoint. If the mean at a given timepoint is BQL then the descriptive statistics will not be presented and will instead display as BQL for the mean and minimum. With the exception of n and max, all other statistics will be missing.

Linear and semi-logarithmic plots of the arithmetic mean plasma concentration by scheduled sampling time will be provided by treatment. These plots will show time in hours. The plots will show all calculated means and will show a reference line for LLOQ.

Linear and semi-logarithmic plots of the individual plasma concentration by actual sampling time will be provided by subject (one subject per page). These plots will show time in hours. Individual plots will use the BQL handling procedure described below for “Pharmacokinetic Parameters”.

All individual subject plasma concentration data will be listed by subject.

16.2.2 Plasma Pharmacokinetic Parameters

Parameter	Description	Analyte	SAS Programming Notes
Cmax	Maximum plasma concentration. Observed peak analyte concentration obtained directly from the experimental data without interpolation, expressed in concentration units	All	Cmax from WNL
Tmax	Time to maximum plasma concentration. First observed time to reach peak analyte concentration obtained directly from the experimental data without interpolation, expressed in time units.	All	Tmax from WNL
AUClast	Area under the concentration-time curve (time 0 to time of last quantifiable concentration).	All	AUClast from WNL
AQ	Abuse quotient	All	Cmax/Tmax
Lz	Terminal phase rate constant calculated by linear regression of the terminal log-linear portion of the concentration vs. time curve. Linear regression of at least three points occurring after Cmax and an r^2 greater than 0.80 are	All	Lambda_z from WNL If Rsq ≤ .80 then parameter is not included

	required to obtain a reliable λz.		
t1/2	Terminal phase half-life expressed in time units. Percent extrapolation less than or equal to 20% and r^2 greater than 0.80 is required to obtain a reliable $t_{1/2}$.	All	HL_Lambda_z from WNL If AUC_%Extrap_obs >20% or Rsq ≤ .80 then parameter is not included

Plasma PK parameters for buprenorphine, nor-buprenorphine, and oxycodone will be estimated using non-compartmental methods with WinNonlin®. The plasma PK parameters will be estimated from the concentration-time profiles, and AUCs will be calculated using linear up / log down. In estimating the PK parameters, BQL values will be set to zero. Actual sampling times, rather than scheduled sampling times, will be used in all computations involving sampling times. If the actual time is missing, the scheduled time may be substituted and flagged.

Determination of points to be included in λz range will follow the Guideline for Defining, Calculating and Summarizing Pharmacokinetic / Pharmacodynamic Parameters (EDSREP 009 R 01).

Descriptive statistics (number of subjects, mean, geometric mean, SD, coefficient of variation (%CV), median, min, and max) will be used to summarize the calculated PK parameters by treatment. For Tmax, only median, min and max will be presented.

17.0 Pharmacodynamic Analysis

All VRH summaries will be performed using the Completer Set. The selected measures will assess VRH associated with Belbuca relative to oxycodone and placebo, and oxycodone relative to placebo.

17.1 Pharmacodynamic Measurements

The PD measurements: V_E, RR, PEF, V_T, and ET_{CO2} will be collected at each of the planned VRH timepoints listed in the Schedule of Assessments (See Appendix 2). Numerous observations will be recorded for each PD measurement at each of these timepoints; however, not all observations are considered clinically valid. Due to the sensitivity of the pneumotachometer machines, small adjustments in posture may be picked up by the machines resulting in false, or "artifact", breaths. For this reason, the following VRH output will be excluded:

- Where ET_{CO2} is missing or marked as ".p" or ".u" by clinic staff
- Where V_E is < 3 L/min or is > 60 L/min
- Where RR is < 4 breaths/min or is > 30 breaths/min

For each of these cases, the entire observation (all VRH measurements) will be excluded. Additionally, any observations recorded during the first 30 seconds of each timepoint ("filetimestamp <= 30" from file) will be excluded as the gas is not considered to have fully infiltrated the breathing machine and residual amounts of oxygen will still be present.

After the above exclusions have been made, one value will be derived for each PD measurement, per subject, per treatment, per timepoint (See table below for calculation of derived PD measurements).

Pharmacodynamic Measurements	
Measurement	**Description**
V_E	Minute ventilation. Volume of gas exhaled per minute from the lungs, expressed in L/min. Calculated as the mean V_E measurement ("MV" from file) per subject, per treatment, per timepoint.
RR	Respiratory rate, expressed in breaths/min.

Pharmacodynamic Measurements	
Measurement	**Description**
	Calculated as the mean RR measurement ["RR (spont)" from file] per subject, per treatment, per timepoint, excluding zeros.
PEF	Peak expiratory flow rate. Maximum speed of expiration, expressed in L/min. Calculated as the mean PEF measurement per subject, per treatment, per timepoint, excluding zeros.
V_T	Tidal volume. Volume of gas displaced between normal inhalation and exhalation when extra effort is not applied, expressed in mL. Calculated as the mean [sum of inspiratory and expiratory tidal volumes ("Tvi" + "Tve" from file)] per subject, per treatment, per timepoint, excluding zeros.
ET_{CO2}	End tidal CO_2. Partial pressure of carbon dioxide at the end of an exhaled breath, expressed in mm Hg. Calculated as the mean ET_{CO2} measurement per subject, per treatment, per timepoint, excluding zeros.
S	Hypercapnic Ventilatory Response, expressed in L/min per mm Hg. Calculated as the slope of the linear regression line created by plotting V_E values versus ET_{CO2} values for each subject per treatment per timepoint. This calculation will use all valid V_E and ET_{CO2} values prior to the calculation of mean V_E and ET_{CO2} values. See SAS code below.
R	Ratio of V_E / ET_{CO2}, expressed in L/min per mm Hg. Calculated as the mean of the ratios of V_E / ET_{CO2} for each subject per treatment per timepoint. This calculation will use all valid V_E and ET_{CO2} values prior to the calculation of mean V_E and ET_{CO2} values.

The SAS PROC REG code for the calculation of S is as follows:

```
proc reg data= VRH;
by subject treatment timepoint;
model VE = ETCO2;
ods output ParameterEstimates = Estimates;
run;
```

PD measurements and derived changes from baseline will be summarized by treatment and scheduled timepoint using descriptive statistics (n, mean, SD, SE, %CV, median, Q1, Q3, min, and max).

Linear plots of the mean (±SD) PD measurements over time will be provided for V_E, RR, PEF, V_T, and ET_{CO2} by treatment. These plots will show time in hours. Box plots of PD Emax parameters by treatment will also be presented.

Individual plots of V_E versus ET_{CO2} will be provided by treatment and timepoint, with a regression line and corresponding regression equation displayed for each treatment.

All valid PD measurements will be listed by subject.

17.2 Pharmacodynamic Parameters

The primary endpoint of interest is the PD parameter of maximum effect (E_{max}) of minute ventilation: V_E E_{max}.

Secondary endpoints of interest include the E_{max} values for the PD measurements: RR, PEF, V_T, and ET_{CO2}.

Pharmacodynamic Parameters	
Parameter	**Description**
E_{max}	Maximum effect, obtained directly from the post-dose mean PD measurements: V_E, RR, PEF, V_T, and ET_{CO2}, and from the postdose derived PD measurements: S and R, per subject and treatment.

The PD measurement E_{max} values will be summarized by treatment using descriptive statistics (n, mean, SD, SE, %CV, median, Q1, Q3, min, and max).

Box plots of the E_{max} of all PD measurements by treatment will be provided. The box plots will include the individual subject E_{max} values.

All PD parameters will be listed by subject.

17.3 Pharmacodynamic Statistical Analyses

The primary endpoint of interest for the analysis is the PD parameter: V_E E_{max}.

The statistical analyses will be performed using the Completer population. The analyses will be repeated with the Partial Completer population for a sensitivity analysis (if not all subjects complete the 6 treatments). The treatment comparisons to assess the respiratory drive of Belbuca relative to oxycodone and placebo will include the following:

- Study Validity (Active Comparator vs. Placebo)
  - Oxycodone 30 mg vs placebo
  - Oxycodone 60 mg vs placebo
- Relative Respiratory Drive (Test vs. Active Comparator)
  - Belbuca 300 ug vs Oxycodone 30 mg
  - Belbuca 300 ug vs Oxycodone 60 mg
  - Belbuca 600 ug vs Oxycodone 30 mg
  - Belbuca 600 ug vs Oxycodone 60 mg
  - Belbuca 900 ug vs Oxycodone 30 mg
  - Belbuca 900 ug vs Oxycodone 60 mg
- Absolute Respiratory Drive (Test vs. Placebo)
  - Belbuca 300 ug vs Placebo
  - Belbuca 600 ug vs Placebo
  - Belbuca 900 ug vs Placebo

As this is a pilot study which is not statistically powered to detect treatment differences, the results of the validity comparison will not affect the reporting of further comparisons.

The SAS mixed effects linear model procedure (PROC MIXED) will be used to construct analysis of variance (ANOVA) models. For each PD measurement: V_E, RR, PEF, V_T, ET_{CO2}, S, and R, an analysis of the E_{max} values will be performed. The models will include terms for treatment, period, and sequence as fixed effects, with subject nested within sequence as a random effect.

The SAS PROC MIXED code for the E_{max} analyses is as follows:

```
proc mixed data= VRH_Emax;
by measurement;
class subject treatment period sequence;
model aval= treatment period sequence;
random subject(sequence);
```

```
lsmeans treatment;
***** Study Validity;
estimate 'Oxy 30 vs Placebo' treatment 0 0 0 1 0 -1 / e cl alpha=0.05;
estimate 'Oxy 60 vs Placebo' treatment 0 0 0 0 1 -1 / e cl alpha=0.05;
***** Relative Respiratory Drive;
estimate 'Bel 300 vs Oxy 30' treatment 1 0 0 -1  0 0 / e cl alpha=0.05;
estimate 'Bel 300 vs Oxy 60' treatment 1 0 0  0 -1 0 / e cl alpha=0.05;
estimate 'Bel 600 vs Oxy 30' treatment 0 1 0 -1  0 0 / e cl alpha=0.05;
estimate 'Bel 600 vs Oxy 60' treatment 0 1 0  0 -1 0 / e cl alpha=0.05;
estimate 'Bel 900 vs Oxy 30' treatment 0 0 1 -1  0 0 / e cl alpha=0.05;
estimate 'Bel 900 vs Oxy 60' treatment 0 0 1  0 -1 0 / e cl alpha=0.05;
***** Absolute Respiratory Drive;
estimate 'Bel 300 vs Placebo' treatment 1 0 0 0 0 0 -1/ e cl alpha=0.05;
estimate 'Bel 600 vs Placebo' treatment 0 1 0 0 0 0 -1/ e cl alpha=0.05;
estimate 'Bel 900 vs Placebo' treatment 0 0 1 0 0 0 -1/ e cl alpha=0.05;
run;
```

A summary table will include the least squares (LS) mean for the test and reference E_{max} value for each parameter, as well as the LS mean difference (test-reference) and 95% confidence interval (CI) and p-value.

18.0 Secondary Endpoints

- Pupillometry
- Change in ratio of minute ventilation over end-tidal CO2

Pupillometry measurements and changes from predose at each post baseline timepoint will be summarized by treatment using descriptive statistics (n, mean, SD, SE, %CV, median, Q1, Q3, min, and max). Pupillometry data will also be listed for each subject by treatment and timepoint.

The change in ratio of minute ventilation over end-tidal CO2 will be presented in a graph, plotting each individual subject's minute ventilation (V_E) versus end tidal CO2 (ET_{CO2}), and also including the regression equations and regression lines for all treatments at each planned timepoint.

19.0 Safety Analyses

19.1 Safety Variables

- Adverse Events (AEs)
- Clinical Laboratory Evaluations
    - Clinical chemistry
    - Hematology
    - Urinalysis
    - Serology
    - Pregnancy test and FSH
    - Urine drug screen
    - Alcohol breath test
- Vital Signs
    - Supine Blood Pressure
        - Systolic blood pressure
        - Diastolic blood pressure
    - Pulse rate
    - Oral body temperature
    - Respiratory Rate

    - Oxygen Saturation
- Electrocardiograms (ECG)
    - Heart rate
    - PR interval
    - QRS-Duration
    - QT interval
    - QTc (Frederica) interval
- Continuous pulse oximetry
- Physical examinations
- Columbia-Suicide Severity Rating Scale (C-SSRS)
- Cardiac Telemetry (continuous measurement during VHR testing)
- COWS (assessments of opiate withdrawal symptoms during Naloxone Challenge)

19.1.1 Adverse Events

Treatment emergence will be evaluated for all AEs. Treatment-emergent adverse events (TEAE) are those which occur after the first dose of study drug.

TEAEs occurring following dosing in a specific period but before dosing in the next period will be attributed to the treatment in that period. If the time is missing for an AE on a dosing day then the AE will be attributed to the treatment given on that day.

The following missing data will be imputed as defined (for calculations only / will not be presented):

- Missing AE start and / or end times for the calculation of onset and duration will be assumed to be at 00:01 for a start time and 23:59 for end times
- Missing AE severity or relationship will be assumed to be severe or related, respectively
- Missing AE start times for the determination of treatment emergence will be assumed to occur after treatment unless partial date documents the AE as happening prior to treatment
- Missing AE start times for the determination of treatment assignment will be assumed to occur after treatment on the recorded date one minute after dosing
- Missing AE start date will be assumed to be after treatment for the determination of TEAE but will not be attributed to a specific treatment.

A summary of number and percentage of subjects reporting TEAEs, TEAEs by severity and relationship, serious AEs (SAEs), and subjects who discontinued study drug due to an AE will be provided.

A summary of the number and percentage of subjects reporting each TEAE, categorized by system organ class and preferred term coded according to the Medical Dictionary for Regulatory Activities (MedDRA), will be presented by treatment, and overall. Counting will be done by subject only, not by event; subjects will only be counted once within each body system or preferred term.

A summary of the number and percentage of subjects reporting each TEAE will be presented according to relationship to study drug (as recorded on the eCRF), by treatment and overall. Subjects with multiple events within a system organ class or preferred term will be counted under the category of their most drug-related event within that system organ class or preferred term.

A summary of the number and percentage of subjects reporting each TEAE will be presented according to severity (as recorded on eCRF), by treatment and overall. Subjects with multiple events within a system organ class or preferred term will be counted under the category of their most severe event within that system organ class or preferred term.

All AEs (including non-treatment-emergent events) recorded on the eCRF will be listed by subject.

A separate listing of AEs leading to study drug discontinuation will be provided.

19.1.2 Deaths and Serious Adverse Events

A listing of deaths and other SAEs will be provided by subject.

19.1.3 Laboratory Data

Clinical laboratory data will be presented using units from the study data tabulation model (SDTM) Controlled Terminology.

Descriptive statistics summarizing continuous laboratory results of clinical chemistry, hematology, and urinalysis (and changes from baseline) by visit will be provided. A summary table of shifts from baseline will also be provided.

All laboratory data will be listed by subject, including laboratory variables not listed in the protocol. A separate listing of out-of-range values will also be provided. Normal ranges will be used directly from the clinical laboratory and will be included in the listings for reference.

19.1.4 Vital Signs

Descriptive statistics summarizing vital signs (and changes from predose) by treatment and scheduled time will be provided.

All vital signs will be listed by subject.

19.1.5 Electrocardiograms

Descriptive statistics summarizing ECG parameters (and changes from predose) by treatment and visit (Day -1 and Day 2 for each treatment period) will be provided. A summary table of shifts from predose will also be provided.

All ECG parameters and the corresponding abnormalities will be listed by subject.

19.1.6 Continuous Pulse Oximetry

Continuous pulse oximetry will be performed throughout the study during the VRH tests, from at least 15 minutes predose until 8 hours postdose. Data will not be recorded in the database but will be used for real-time safety monitoring. Oxygen saturation data will be presented in a descriptive statistics summary table by treatment and timepoint. Individual subject data will be presented in a listing. Observations of abnormal data that lead to medical treatment, non-scheduled procedures and/or discontinuation from the study will be recorded as AEs.

19.1.7 Physical Examinations

Physical examination result shifts from Baseline (screening visit) to Day 2 of each treatment period will be summarized by treatment. All physical examination data will also be listed by subject.

19.1.8 Cardiac Telemetry

A listing of the start and stop times for cardiac telemetry will be provided. Any clinically significant abnormal objective test findings will be recorded as AEs..

19.1.9 Columbia-Suicide Severity Rating Scale

The C-SSRS data will be listed by subject and timepoint.

19.1.10 Clinical Opiate Withdrawal Scale

COWS results will be listed by subject.

20.0 References

SAS Institute, Inc., SAS® Version 9.4 software, Cary, NC.

Appendix 1: Glossary of Abbreviations

Glossary of Abbreviations:	
AE	Adverse event
ADaM	Analysis data model
AUC	Area under the curve
ANOVA	Analysis of variance
BMI	Body mass index
BP	Blood pressure
BQL	Below the quantifiable limit
CDISC	Clinical Data Interchange Standard Consortium
CI	Confidence interval
COWS	Clinical Opiate Withdrawal Scale
CO2	Carbon dioxide
CSR	Clinical study report
C-SSRS	Columbia Suicide Severity Rating Scale
CTMS	Clinical Trial Management System
CV	Coefficient of variation
ECG	Electrocardiogram
eCRF	Electronic case report form
E_{MAX}	Maximum effect
EDS	Early Development Services
FSH	Follicle stimulating hormone
HR	Heart rate
ICH	The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
LLOQ	Lower limit of quantification
LOCF	Last observation carried forward
MedDRA	Medical Dictionary for Regulatory Activities
PD	Pharmacodynamic
PEF	Peak expiratory flow
PK	Pharmacokinetic
QA'd	Quality assured
QC'd	Quality controlled

QTc	Corrected QT interval
RR	Respiration rate
SAP	Statistical analysis plan
SAE	Serious adverse event
SDTM	Study data tabulation model
SPO2	Peripheral capillary oxygen saturation
TEAE	Treatment-emergent adverse event
TFL(s)	Tables, figures and listings
V_E	Minute ventilation
VRH	Ventilatory response to hypercapnia
V_T	Tidal volume
WHO-DDE	World Health Organization – Drug Dictionary Enhanced
WNL	WinNonlin

Appendix 2: Schedule of Assessments

	Screening	Inpatient Visit			Early Termination	Follow-Up Call
Visit ID	**V1**	**V2-V7[a]**			**ET**	**V9**
Study Day(s) **Procedures**	**-28 to -2**	**-1**	**1**	**2**		7 days from final IMP (+/- 2 days)
Informed consent	X					
Eligibility criteria	X	confirm				
Demographics	X					
Medical history, including recreational drug use history	X	update				
Physical examination	X			X	X[b]	
Oral mucosa examination	X	X				
Pregnancy test[c]	X	X				
Follicle stimulating hormone and estradiol level[d]	X					
Height, weight, BMI	X					
Blood pressure, heart rate, and respiration rate	X	X	X[e]	X	X	
Temperature	X	X	X[e]	X	X	
O_2 saturation	X		X[e]	X	X	
Continuous pulse oximetry			X[f]			
12-lead ECG	X	X		X	X	
Continuous cardiac telemetry			X[g]			
Chemistry and hematology labs[h]	X	X			X	
Viral serology (HBsAG, anti-HCV, HIV)	X					
Urinalysis	X	X			X	
Alcohol breathalyzer/urine drug screen	X	X				
Naloxone Challenge[i]		X				
Randomization (first treatment period only)			X			

IMP administration			X			
Pupillometry			X[e]			
Ventilatory Response to Hypercapnia	X		X[j]			
PK[k]			X			
C-SSRS[l]	X	X			X	
Adverse events			X	X	X	X
Prior/Concomitant medications	X	X	X	X	X	X
Discharge from clinic				X		

BMI=body mass index; C-SSRS=Columbia-Suicide Severity Rating Scale; ECG=electrocardiogram; ET=early termination; HBsAg=hepatitis B surface antigen; HCV=hepatitis C virus; HIV=human immunodeficiency virus; ID=identification; IMP=investigational medicinal product; PK=pharmacokinetics

[a] Each treatment period will be separated by at least 7 days.

[b] Physical examination to be completed at ET at discretion of investigator. Unscheduled symptom-directed PEs may be conducted at any time per the investigator's discretion.

[c] Serum pregnancy test will be done for all female subjects at screening. Urine pregnancy test will be done for all female subjects at check-in to each period.

[d] Postmenopausal female subjects only to confirm postmenopausal status.

[e] Vital signs, and pupillometry collected at predose and 0.5, 1, 1.5, 2, 2.5, 3, and 4 hours postdose. Body temperature collected once predose each treatment period.

[f] Continuous pulse oximetry from at least 15 minutes predose through 8 hours postdose, and recorded at 0.5, 1, 1.5, 2, 2.5, 3, 4, 6, and 8 hours postdose.

[g] Continuous cardiac telemetry during VRH procedures from at least 15 minutes predose until at least 4 hours postdose.

[h] Creatinine clearance and thyroid stimulating hormone (TSH) will be measured at screening only.

[i] Naloxone challenge will be done during Treatment Period 1 and will consist of vital signs (BP, HR, RR and O_2 Saturation) at least 30 minutes before naloxone administration and at 5 minutes, 30 minutes and 60 minutes after administration. Clinical Opiate Withdrawal Scale (COWS) associated with the naloxone challenge will occur immediately predose and within 1 minute and 5 minutes after administration of naloxone.

[j] VRH at predose and 0.5, 1, 2, 3, and 4 hours postdose.

[k] PK at predose, 0.5, 1, 2, 3, 4, and 6 hours postdose.

[l] C-SSRS Baseline version will be used at screening. At the subsequent visits, C-SSRS Since Last Visit version will be used.

Appendix 3: List of End of Text Outputs

End of Text Tables and Figures:		
Output	**Title**	**Analysis Set**
	Demographic Data	
Table 14.1.1	Summary of Analysis Sets	All Analysis Sets
Table 14.1.2	Summary of Subject Disposition	All Analysis Sets
Table 14.1.3	Summary of Dosing	Safety
Table 14.1.4	Summary of Demographics	All Analysis Sets
Table 14.1.5	Summary of Recreational Drug Use History	Safety
	PD and PK Summaries	
Table 14.2.1.1	Summary of VRH Measurements and Changes from Baseline	Completer
Table 14.2.1.2	Summary of VRH Parameters	Completer
Table 14.2.2	Statistical Analysis of Respiratory Drive of Belbuca	Completer
Table 14.2.3	Statistical Analysis of Respiratory Drive of Belbuca	Partial Completer
Figure 14.2.4.1	Plot of Mean (±SD) Minute Ventilation over Time	Completer
Figure 14.2.4.2	Box Plot of Minute Ventilation E_{max} by Treatment	Completer
Figure 14.2.5.1	Plot of Mean (±SD) Respiratory Rate over Time	Completer
Figure 14.2.5.2	Box Plot of Respiratory Rate E_{max} by Treatment	Completer
Figure 14.2.6.1	Plot of Mean (±SD) Peak Expiratory Flow Rate over Time	Completer
Figure 14.2.6.2	Box Plot of Respiratory Rate E_{max} by Treatment	Completer
Figure 14.2.7.1	Plot of Mean (±SD) Tidal Volume over Time	Completer
Figure 14.2.7.2	Box Plot of Tidal Volume E_{max} by Treatment	Completer
Figure 14.2.8.1	Plot of Mean (±SD) End Tidal CO_2 over Time	Completer
Figure 14.2.8.2	Box Plot of End Tidal CO_2 E_{max} by Treatment	Completer
Figure 14.2.9.1	Plot of Individual Minute Ventilation versus End Tidal CO_2	Completer
Figure 14.2.9.2	Box Plot of Slope E_{max} by Treatment	Completer
Figure 14.2.9.3	Box Plot of Ratio E_{max} by Treatment	Completer
Table 14.2.10	Summary of Pupillometry and Changes from Predose	Completer
Table 14.2.11.1	Summary of Plasma Concentrations of Belbuca	Safety
Table 14.2.11.2	Summary of Plasma Concentrations of Oxycodone	Safety
Table 14.2.12.1	Summary of Plasma Pharmacokinetic Parameters of Belbuca	PK
Table 14.2.12.2	Summary of Plasma Pharmacokinetic Parameters of Oxycodone	PK
Figure 14.2.13.1	Plot of Mean (±SD) Plasma Concentrations Versus Time on a Linear Scale - Belbuca	PK
Figure 14.2.13.2	Plot of Mean (±SD) Plasma Concentrations Versus Time on a	PK

	Linear Scale - Oxycodone	
Figure 14.2.13.3	Plot of Mean (±SD) Plasma Concentrations Versus Time on a Semi-Log Scale - Belbuca	PK
Figure 14.2.13.4	Plot of Mean (±SD) Plasma Concentrations Versus Time on a Semi-Log Scale - Oxycodone	PK
Figure 14.2.13.5	Plot of Individual Plasma Concentrations Versus Time on a Linear Scale - Belbuca	PK
Figure 14.2.13.6	Plot of Individual Plasma Concentrations Versus Time on a Linear Scale - Oxycodone	PK
Figure 14.2.13.7	Plot of Individual Plasma Concentrations Versus Time on a Semi-Log Scale - Belbuca	PK
Figure 14.2.13.8	Plot of Individual Plasma Concentrations Versus Time on a Semi-Log Scale - Oxycodone	PK
	Safety Data	
Table 14.3.1.1	Summary of Adverse Events	Safety
Table 14.3.1.2	Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term	Safety
Table 14.3.1.3	Summary of Treatment Emergent Adverse Events by Relationship to Study Drug	Safety
Table 14.3.1.4	Summary of Treatment Emergent Adverse Events by Severity	Safety
Table 14.3.2	Listing of Deaths and Other Serious Adverse Events	All Subjects
Table 14.3.3	Not part of the TFLs – Reserved for narratives in the CSR	
Table 14.3.4	Listing of Abnormal Laboratory Values	All Subjects
Table 14.3.5.1	Summary of Laboratory Results	Safety
Table 14.3.5.2	Summary of Laboratory Shifts from Baseline	Safety
Table 14.3.6	Summary of Vital Signs	Safety
Table 14.3.7	Summary of Continuous Oxygen Saturation Monitoring	Safety
Table 14.3.8.1	Summary of 12-Lead Electrocardiograms	Safety
Table 14.3.8.2	Summary of 12-Lead Electrocardiograms Shifts from Predose	Safety
Table 14.3.9	Summary of Physical Exam Shifts from Baseline	Safety

End of Text Listings:	
Output	**Title**
Listing 16.2.1.1	Subject Disposition
Listing 16.2.1.2	Medical History
Listing 16.2.1.3	Prior and Concomitant Medications
Listing 16.2.2	Not part of the TFLs – Reserved for protocol deviations in the CSR
Listing 16.2.3	Analysis Populations
Listing 16.2.4.1	Subject Demographics

Listing 16.2.4.2	Recreational Drug History
Listing 16.2.5.1	Naloxone Challenge Dosing
Listing 16.2.5.2	Clinical Opiate Withdrawal Scale Results
Listing 16.2.5.3	Study Drug Administration
Listing 16.2.6.1	VRH Measurements
Listing 16.2.6.2	VRH Parameters
Listing 16.2.6.3.1	Listing of Plasma Concentrations of Belbuca
Listing 16.2.6.3.2	Listing of Plasma Concentrations of Oxycodone
Listing 16.2.6.4.1	Listing of Plasma Pharmacokinetic Parameters of Belbuca
Listing 16.2.6.4.2	Listing of Plasma Pharmacokinetic Parameters of Oxycodone
Listing 16.2.6.5	Listing of Pupillometry
Listing 16.2.7.1	Adverse Events
Listing 16.2.7.2	Adverse Events Resulting in Discontinuation
Listing 16.2.8.1	Clinical Laboratory Results – Hematology
Listing 16.2.8.2	Clinical Laboratory Results – Chemistry
Listing 16.2.8.3	Clinical Laboratory Results – Urinalysis
Listing 16.2.8.4	Clinical Laboratory Results – Additional
Listing 16.2.8.5	Clinical Laboratory Results – Urine Drug Screen and Alcohol Breath
Listing 16.2.9	Vital Signs
Listing 16.2.10	12-Lead Electrocardiograms
Listing 16.2.11	Physical Examinations
Listing 16.2.12	Columbia-Suicide Severity Rating Scale Results
Listing 16.2.13	SPO2 Monitoring
Listing 16.2.14	Cardiac Telemetry

Other Appendix Outputs:	
Output	**Title**
Appendix 16.1.9.2	Statistical Appendices

Appendix 4: Shells for Post-Text Tables, Figures and Listings

Shells are provided in a separate document.

21.0 Document History

Version Date	Modified/Reviewed By	Brief Summary of Changes (if created from a template, include template code)
23-Sep-2019	Jacqueline Cater Reilly Reis Thomas Thompson	

Effective Date	Version	Modified/Reviewed By	Brief Summary of Changes (if created from a template, include template code)

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information

Class	Levels	Values
SUBJID	15	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017
TRTPN	6	1 2 3 4 5 6
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA

Dimensions

Covariance Parameters	2
Columns in X	19
Columns in Z	15
Subjects	1
Max Obs per Subject	90

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Number of Observations	
Number of Observations Read	90
Number of Observations Used	90
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	425.16851375	
1	1	403.50606077	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID(ARMCD)	5.9883
Residual	6.3569

Fit Statistics	
-2 Res Log Likelihood	403.5
AIC (Smaller is Better)	407.5
AICC (Smaller is Better)	407.7
BIC (Smaller is Better)	408.9

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	65	2.92	0.0193
APERIOD	5	65	0.49	0.7801
ARMCD	5	9	0.77	0.5916

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	1
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	1
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Oxy 30 vs Placebo	1.2467	0.9248	65	1.35	0.1823	0.05	-0.6002	3.0936
Oxy 60 vs Placebo	2.1371	0.9248	65	2.31	0.0240	0.05	0.2901	3.9840
Bel 300 vs Oxy 30	-2.3279	0.9248	65	-2.52	0.0143	0.05	-4.1748	-0.4810
Bel 300 vs Oxy 60	-3.2183	0.9248	65	-3.48	0.0009	0.05	-5.0652	-1.3714
Bel 600 vs Oxy 30	-0.09483	0.9227	65	-0.10	0.9185	0.05	-1.9376	1.7479
Bel 600 vs Oxy 60	-0.9852	0.9248	65	-1.07	0.2907	0.05	-2.8321	0.8617
Bel 900 vs Oxy 30	-0.3557	0.9248	65	-0.38	0.7018	0.05	-2.2026	1.4912
Bel 900 vs Oxy 60	-1.2461	0.9227	65	-1.35	0.1816	0.05	-3.0888	0.5967
Bel 300 vs Placebo	-1.0812	0.9227	65	-1.17	0.2455	0.05	-2.9240	0.7615
Bel 600 vs Placebo	1.1519	0.9248	65	1.25	0.2174	0.05	-0.6950	2.9988
Bel 900 vs Placebo	0.8910	0.9248	65	0.96	0.3389	0.05	-0.9559	2.7379

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Least Squares Means

Effect	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	40.6766	0.9195	65	44.24	<.0001	0.05	38.8402	42.5129
TRTPN	2	42.9097	0.9195	65	46.67	<.0001	0.05	41.0733	44.7460
TRTPN	3	42.6488	0.9195	65	46.38	<.0001	0.05	40.8124	44.4851
TRTPN	4	43.0045	0.9195	65	46.77	<.0001	0.05	41.1682	44.8408
TRTPN	5	43.8948	0.9195	65	47.74	<.0001	0.05	42.0585	45.7312
TRTPN	6	41.7578	0.9195	65	45.41	<.0001	0.05	39.9215	43.5941

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	2	-2.2331	0.9248	65	-2.41	0.0186	0.05	-4.0800	-0.3862
TRTPN	1	3	-1.9722	0.9248	65	-2.13	0.0367	0.05	-3.8191	-0.1253
TRTPN	1	4	-2.3279	0.9248	65	-2.52	0.0143	0.05	-4.1748	-0.4810
TRTPN	1	5	-3.2183	0.9248	65	-3.48	0.0009	0.05	-5.0652	-1.3714
TRTPN	1	6	-1.0812	0.9227	65	-1.17	0.2455	0.05	-2.9240	0.7615
TRTPN	2	3	0.2609	0.9248	65	0.28	0.7788	0.05	-1.5860	2.1078
TRTPN	2	4	-0.09483	0.9227	65	-0.10	0.9185	0.05	-1.9376	1.7479
TRTPN	2	5	-0.9852	0.9248	65	-1.07	0.2907	0.05	-2.8321	0.8617
TRTPN	2	6	1.1519	0.9248	65	1.25	0.2174	0.05	-0.6950	2.9988
TRTPN	3	4	-0.3557	0.9248	65	-0.38	0.7018	0.05	-2.2026	1.4912
TRTPN	3	5	-1.2461	0.9227	65	-1.35	0.1816	0.05	-3.0888	0.5967
TRTPN	3	6	0.8910	0.9248	65	0.96	0.3389	0.05	-0.9559	2.7379
TRTPN	4	5	-0.8903	0.9248	65	-0.96	0.3392	0.05	-2.7372	0.9566

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=ETCOEMAX

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	4	6	1.2467	0.9248	65	1.35	0.1823	0.05	-0.6002	3.0936
TRTPN	5	6	2.1371	0.9248	65	2.31	0.0240	0.05	0.2901	3.9840

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information

Class	Levels	Values
SUBJID	15	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017
TRTPN	6	1 2 3 4 5 6
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA

Dimensions

Covariance Parameters	2
Columns in X	19
Columns in Z	15
Subjects	1
Max Obs per Subject	90

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Number of Observations

Number of Observations Read	90
Number of Observations Used	90
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1541.87045175	
1	1	1532.27894557	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID(ARMCD)	13297907
Residual	28686215

Fit Statistics

-2 Res Log Likelihood	1532.3
AIC (Smaller is Better)	1536.3
AICC (Smaller is Better)	1536.4
BIC (Smaller is Better)	1537.7

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	65	2.93	0.0190
APERIOD	5	65	2.16	0.0699
ARMCD	5	9	0.68	0.6506

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	1
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	1
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Oxy 30 vs Placebo	-794.77	1964.49	65	-0.40	0.6871	0.05	-4718.12	3128.58
Oxy 60 vs Placebo	-5228.92	1964.49	65	-2.66	0.0098	0.05	-9152.27	-1305.57
Bel 300 vs Oxy 30	2034.61	1964.49	65	1.04	0.3042	0.05	-1888.74	5957.96
Bel 300 vs Oxy 60	6468.76	1964.49	65	3.29	0.0016	0.05	2545.41	10392
Bel 600 vs Oxy 30	1022.24	1960.08	65	0.52	0.6038	0.05	-2892.31	4936.78
Bel 600 vs Oxy 60	5456.39	1964.49	65	2.78	0.0072	0.05	1533.04	9379.74
Bel 900 vs Oxy 30	1726.13	1964.49	65	0.88	0.3828	0.05	-2197.22	5649.48
Bel 900 vs Oxy 60	6160.28	1960.08	65	3.14	0.0025	0.05	2245.73	10075
Bel 300 vs Placebo	1239.84	1960.08	65	0.63	0.5292	0.05	-2674.70	5154.39
Bel 600 vs Placebo	227.47	1964.49	65	0.12	0.9082	0.05	-3695.88	4150.82
Bel 900 vs Placebo	931.36	1964.49	65	0.47	0.6370	0.05	-2991.99	4854.71

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Least Squares Means

Effect	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	23741	1691.76	65	14.03	<.0001	0.05	20362	27120
TRTPN	2	22729	1691.76	65	13.43	<.0001	0.05	19350	26107
TRTPN	3	23433	1691.76	65	13.85	<.0001	0.05	20054	26811
TRTPN	4	21706	1691.76	65	12.83	<.0001	0.05	18328	25085
TRTPN	5	17272	1691.76	65	10.21	<.0001	0.05	13894	20651
TRTPN	6	22501	1691.76	65	13.30	<.0001	0.05	19123	25880

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	2	1012.37	1964.49	65	0.52	0.6081	0.05	-2910.98	4935.72
TRTPN	1	3	308.48	1964.49	65	0.16	0.8757	0.05	-3614.87	4231.83
TRTPN	1	4	2034.61	1964.49	65	1.04	0.3042	0.05	-1888.74	5957.96
TRTPN	1	5	6468.76	1964.49	65	3.29	0.0016	0.05	2545.41	10392
TRTPN	1	6	1239.84	1960.08	65	0.63	0.5292	0.05	-2674.70	5154.39
TRTPN	2	3	-703.89	1964.49	65	-0.36	0.7213	0.05	-4627.24	3219.46
TRTPN	2	4	1022.24	1960.08	65	0.52	0.6038	0.05	-2892.31	4936.78
TRTPN	2	5	5456.39	1964.49	65	2.78	0.0072	0.05	1533.04	9379.74
TRTPN	2	6	227.47	1964.49	65	0.12	0.9082	0.05	-3695.88	4150.82
TRTPN	3	4	1726.13	1964.49	65	0.88	0.3828	0.05	-2197.22	5649.48
TRTPN	3	5	6160.28	1960.08	65	3.14	0.0025	0.05	2245.73	10075
TRTPN	3	6	931.36	1964.49	65	0.47	0.6370	0.05	-2991.99	4854.71
TRTPN	4	5	4434.15	1964.49	65	2.26	0.0274	0.05	510.80	8357.50

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=MVMIEMAX

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	4	6	-794.77	1964.49	65	-0.40	0.6871	0.05	-4718.12	3128.58
TRTPN	5	6	-5228.92	1964.49	65	-2.66	0.0098	0.05	-9152.27	-1305.57

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information

Class	Levels	Values
SUBJID	15	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017
TRTPN	6	1 2 3 4 5 6
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA

Dimensions

Covariance Parameters	2
Columns in X	19
Columns in Z	15
Subjects	1
Max Obs per Subject	90

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Number of Observations

Number of Observations Read	90
Number of Observations Used	90
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	668.81167810	
1	1	659.34634479	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID(ARMCD)	99.2034
Residual	216.26

Fit Statistics

-2 Res Log Likelihood	659.3
AIC (Smaller is Better)	663.3
AICC (Smaller is Better)	663.5
BIC (Smaller is Better)	664.8

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	65	2.64	0.0313
APERIOD	5	65	2.53	0.0374
ARMCD	5	9	0.58	0.7181

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	1
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	1
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Oxy 30 vs Placebo	0.01627	5.3939	65	0.00	0.9976	0.05	-10.7560	10.7886
Oxy 60 vs Placebo	-13.6055	5.3939	65	-2.52	0.0141	0.05	-24.3778	-2.8332
Bel 300 vs Oxy 30	2.8228	5.3939	65	0.52	0.6025	0.05	-7.9495	13.5951
Bel 300 vs Oxy 60	16.4446	5.3939	65	3.05	0.0033	0.05	5.6723	27.2169
Bel 600 vs Oxy 30	1.6470	5.3818	65	0.31	0.7606	0.05	-9.1012	12.3951
Bel 600 vs Oxy 60	15.2687	5.3939	65	2.83	0.0062	0.05	4.4964	26.0410
Bel 900 vs Oxy 30	1.9547	5.3939	65	0.36	0.7182	0.05	-8.8176	12.7270
Bel 900 vs Oxy 60	15.5765	5.3818	65	2.89	0.0052	0.05	4.8283	26.3246
Bel 300 vs Placebo	2.8391	5.3818	65	0.53	0.5996	0.05	-7.9090	13.5872
Bel 600 vs Placebo	1.6632	5.3939	65	0.31	0.7588	0.05	-9.1091	12.4355
Bel 900 vs Placebo	1.9710	5.3939	65	0.37	0.7160	0.05	-8.8013	12.7433

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Least Squares Means

Effect	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	62.0303	4.6372	65	13.38	<.0001	0.05	52.7692	71.2915
TRTPN	2	60.8544	4.6372	65	13.12	<.0001	0.05	51.5933	70.1156
TRTPN	3	61.1622	4.6372	65	13.19	<.0001	0.05	51.9011	70.4233
TRTPN	4	59.2075	4.6372	65	12.77	<.0001	0.05	49.9464	68.4686
TRTPN	5	45.5857	4.6372	65	9.83	<.0001	0.05	36.3246	54.8469
TRTPN	6	59.1912	4.6372	65	12.76	<.0001	0.05	49.9301	68.4524

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	2	1.1759	5.3939	65	0.22	0.8281	0.05	-9.5964	11.9482
TRTPN	1	3	0.8681	5.3939	65	0.16	0.8726	0.05	-9.9042	11.6404
TRTPN	1	4	2.8228	5.3939	65	0.52	0.6025	0.05	-7.9495	13.5951
TRTPN	1	5	16.4446	5.3939	65	3.05	0.0033	0.05	5.6723	27.2169
TRTPN	1	6	2.8391	5.3818	65	0.53	0.5996	0.05	-7.9090	13.5872
TRTPN	2	3	-0.3078	5.3939	65	-0.06	0.9547	0.05	-11.0800	10.4645
TRTPN	2	4	1.6470	5.3818	65	0.31	0.7606	0.05	-9.1012	12.3951
TRTPN	2	5	15.2687	5.3939	65	2.83	0.0062	0.05	4.4964	26.0410
TRTPN	2	6	1.6632	5.3939	65	0.31	0.7588	0.05	-9.1091	12.4355
TRTPN	3	4	1.9547	5.3939	65	0.36	0.7182	0.05	-8.8176	12.7270
TRTPN	3	5	15.5765	5.3818	65	2.89	0.0052	0.05	4.8283	26.3246
TRTPN	3	6	1.9710	5.3939	65	0.37	0.7160	0.05	-8.8013	12.7433
TRTPN	4	5	13.6217	5.3939	65	2.53	0.0140	0.05	2.8495	24.3940

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=PEFMEMAX

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	4	6	0.01627	5.3939	65	0.00	0.9976	0.05	-10.7560	10.7886
TRTPN	5	6	-13.6055	5.3939	65	-2.52	0.0141	0.05	-24.3778	-2.8332

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information

Class	Levels	Values
SUBJID	15	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017
TRTPN	6	1 2 3 4 5 6
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA

Dimensions

Covariance Parameters	2
Columns in X	19
Columns in Z	15
Subjects	1
Max Obs per Subject	90

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Number of Observations

Number of Observations Read	90
Number of Observations Used	90
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	983.84438280	
1	1	974.53438815	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID(ARMCD)	6936.53
Residual	15320

Fit Statistics

-2 Res Log Likelihood	974.5
AIC (Smaller is Better)	978.5
AICC (Smaller is Better)	978.7
BIC (Smaller is Better)	980.0

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	65	3.72	0.0051
APERIOD	5	65	2.32	0.0528
ARMCD	5	9	0.89	0.5270

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	1
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	1
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Oxy 30 vs Placebo	-20.2097	45.3991	65	-0.45	0.6577	0.05	-110.88	70.4586
Oxy 60 vs Placebo	-129.70	45.3991	65	-2.86	0.0057	0.05	-220.37	-39.0311
Bel 300 vs Oxy 30	64.5958	45.3991	65	1.42	0.1596	0.05	-26.0726	155.26
Bel 300 vs Oxy 60	174.09	45.3991	65	3.83	0.0003	0.05	83.4171	264.75
Bel 600 vs Oxy 30	20.6471	45.2972	65	0.46	0.6500	0.05	-69.8177	111.11
Bel 600 vs Oxy 60	130.14	45.3991	65	2.87	0.0056	0.05	39.4684	220.81
Bel 900 vs Oxy 30	49.7034	45.3991	65	1.09	0.2776	0.05	-40.9650	140.37
Bel 900 vs Oxy 60	159.19	45.2972	65	3.51	0.0008	0.05	68.7282	249.66
Bel 300 vs Placebo	44.3861	45.2972	65	0.98	0.3308	0.05	-46.0788	134.85
Bel 600 vs Placebo	0.4374	45.3991	65	0.01	0.9923	0.05	-90.2310	91.1057
Bel 900 vs Placebo	29.4936	45.3991	65	0.65	0.5182	0.05	-61.1747	120.16

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Least Squares Means

Effect	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	586.67	38.9492	65	15.06	<.0001	0.05	508.88	664.46
TRTPN	2	542.72	38.9492	65	13.93	<.0001	0.05	464.93	620.51
TRTPN	3	571.78	38.9492	65	14.68	<.0001	0.05	493.99	649.56
TRTPN	4	522.07	38.9492	65	13.40	<.0001	0.05	444.29	599.86
TRTPN	5	412.58	38.9492	65	10.59	<.0001	0.05	334.80	490.37
TRTPN	6	542.28	38.9492	65	13.92	<.0001	0.05	464.50	620.07

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	2	43.9487	45.3991	65	0.97	0.3366	0.05	-46.7197	134.62
TRTPN	1	3	14.8924	45.3991	65	0.33	0.7439	0.05	-75.7759	105.56
TRTPN	1	4	64.5958	45.3991	65	1.42	0.1596	0.05	-26.0726	155.26
TRTPN	1	5	174.09	45.3991	65	3.83	0.0003	0.05	83.4171	264.75
TRTPN	1	6	44.3861	45.2972	65	0.98	0.3308	0.05	-46.0788	134.85
TRTPN	2	3	-29.0563	45.3991	65	-0.64	0.5244	0.05	-119.72	61.6121
TRTPN	2	4	20.6471	45.2972	65	0.46	0.6500	0.05	-69.8177	111.11
TRTPN	2	5	130.14	45.3991	65	2.87	0.0056	0.05	39.4684	220.81
TRTPN	2	6	0.4374	45.3991	65	0.01	0.9923	0.05	-90.2310	91.1057
TRTPN	3	4	49.7034	45.3991	65	1.09	0.2776	0.05	-40.9650	140.37
TRTPN	3	5	159.19	45.2972	65	3.51	0.0008	0.05	68.7282	249.66
TRTPN	3	6	29.4936	45.3991	65	0.65	0.5182	0.05	-61.1747	120.16
TRTPN	4	5	109.49	45.3991	65	2.41	0.0187	0.05	18.8213	200.16

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=REMAX

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	4	6	-20.2097	45.3991	65	-0.45	0.6577	0.05	-110.88	70.4586
TRTPN	5	6	-129.70	45.3991	65	-2.86	0.0057	0.05	-220.37	-39.0311

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information

Class	Levels	Values
SUBJID	15	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017
TRTPN	6	1 2 3 4 5 6
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA

Dimensions

Covariance Parameters	2
Columns in X	19
Columns in Z	15
Subjects	1
Max Obs per Subject	90

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Number of Observations	
Number of Observations Read	90
Number of Observations Used	90
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	447.68859180	
1	1	419.42531502	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID(ARMCD)	9.4252
Residual	7.6646

Fit Statistics	
-2 Res Log Likelihood	419.4
AIC (Smaller is Better)	423.4
AICC (Smaller is Better)	423.6
BIC (Smaller is Better)	424.8

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	65	0.80	0.5523
APERIOD	5	65	1.02	0.4119
ARMCD	5	9	0.61	0.6987

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	1
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	1
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Oxy 30 vs Placebo	-1.5420	1.0154	65	-1.52	0.1337	0.05	-3.5700	0.4860
Oxy 60 vs Placebo	-1.8452	1.0154	65	-1.82	0.0738	0.05	-3.8732	0.1827
Bel 300 vs Oxy 30	0.4076	1.0154	65	0.40	0.6894	0.05	-1.6204	2.4356
Bel 300 vs Oxy 60	0.7109	1.0154	65	0.70	0.4864	0.05	-1.3171	2.7388
Bel 600 vs Oxy 30	0.4711	1.0132	65	0.46	0.6435	0.05	-1.5524	2.4945
Bel 600 vs Oxy 60	0.7743	1.0154	65	0.76	0.4485	0.05	-1.2537	2.8023
Bel 900 vs Oxy 30	0.06312	1.0154	65	0.06	0.9506	0.05	-1.9649	2.0911
Bel 900 vs Oxy 60	0.3664	1.0132	65	0.36	0.7188	0.05	-1.6571	2.3898
Bel 300 vs Placebo	-1.1344	1.0132	65	-1.12	0.2670	0.05	-3.1578	0.8890
Bel 600 vs Placebo	-1.0710	1.0154	65	-1.05	0.2955	0.05	-3.0989	0.9570
Bel 900 vs Placebo	-1.4789	1.0154	65	-1.46	0.1501	0.05	-3.5069	0.5491

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Least Squares Means

Effect	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	15.5293	1.0828	65	14.34	<.0001	0.05	13.3667	17.6918
TRTPN	2	15.5927	1.0828	65	14.40	<.0001	0.05	13.4302	17.7552
TRTPN	3	15.1848	1.0828	65	14.02	<.0001	0.05	13.0222	17.3473
TRTPN	4	15.1217	1.0828	65	13.97	<.0001	0.05	12.9591	17.2842
TRTPN	5	14.8184	1.0828	65	13.69	<.0001	0.05	12.6559	16.9809
TRTPN	6	16.6637	1.0828	65	15.39	<.0001	0.05	14.5011	18.8262

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	2	-0.06343	1.0154	65	-0.06	0.9504	0.05	-2.0914	1.9645
TRTPN	1	3	0.3445	1.0154	65	0.34	0.7355	0.05	-1.6835	2.3725
TRTPN	1	4	0.4076	1.0154	65	0.40	0.6894	0.05	-1.6204	2.4356
TRTPN	1	5	0.7109	1.0154	65	0.70	0.4864	0.05	-1.3171	2.7388
TRTPN	1	6	-1.1344	1.0132	65	-1.12	0.2670	0.05	-3.1578	0.8890
TRTPN	2	3	0.4079	1.0154	65	0.40	0.6892	0.05	-1.6201	2.4359
TRTPN	2	4	0.4711	1.0132	65	0.46	0.6435	0.05	-1.5524	2.4945
TRTPN	2	5	0.7743	1.0154	65	0.76	0.4485	0.05	-1.2537	2.8023
TRTPN	2	6	-1.0710	1.0154	65	-1.05	0.2955	0.05	-3.0989	0.9570
TRTPN	3	4	0.06312	1.0154	65	0.06	0.9506	0.05	-1.9649	2.0911
TRTPN	3	5	0.3664	1.0132	65	0.36	0.7188	0.05	-1.6571	2.3898
TRTPN	3	6	-1.4789	1.0154	65	-1.46	0.1501	0.05	-3.5069	0.5491
TRTPN	4	5	0.3032	1.0154	65	0.30	0.7662	0.05	-1.7247	2.3312

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=RRSPEMAX

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	4	6	-1.5420	1.0154	65	-1.52	0.1337	0.05	-3.5700	0.4860
TRTPN	5	6	-1.8452	1.0154	65	-1.82	0.0738	0.05	-3.8732	0.1827

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information

Class	Levels	Values
SUBJID	15	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017
TRTPN	6	1 2 3 4 5 6
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA

Dimensions

Covariance Parameters	2
Columns in X	19
Columns in Z	15
Subjects	1
Max Obs per Subject	90

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Number of Observations	
Number of Observations Read	90
Number of Observations Used	90
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1156.00805775	
1	1	1151.83225999	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID(ARMCD)	44274
Residual	176454

Fit Statistics	
-2 Res Log Likelihood	1151.8
AIC (Smaller is Better)	1155.8
AICC (Smaller is Better)	1156.0
BIC (Smaller is Better)	1157.2

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	65	2.66	0.0299
APERIOD	5	65	3.33	0.0096
ARMCD	5	9	1.24	0.3681

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	1
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	1
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Oxy 30 vs Placebo	-72.0201	154.07	65	-0.47	0.6417	0.05	-379.73	235.69
Oxy 60 vs Placebo	-336.37	154.07	65	-2.18	0.0326	0.05	-644.08	-28.6636
Bel 300 vs Oxy 30	200.18	154.07	65	1.30	0.1984	0.05	-107.52	507.89
Bel 300 vs Oxy 60	464.53	154.07	65	3.01	0.0037	0.05	156.83	772.24
Bel 600 vs Oxy 30	165.60	153.73	65	1.08	0.2854	0.05	-141.42	472.62
Bel 600 vs Oxy 60	429.95	154.07	65	2.79	0.0069	0.05	122.24	737.66
Bel 900 vs Oxy 30	193.57	154.07	65	1.26	0.2135	0.05	-114.14	501.28
Bel 900 vs Oxy 60	457.92	153.73	65	2.98	0.0041	0.05	150.90	764.94
Bel 300 vs Placebo	128.16	153.73	65	0.83	0.4075	0.05	-178.85	435.18
Bel 600 vs Placebo	93.5803	154.07	65	0.61	0.5457	0.05	-214.13	401.29
Bel 900 vs Placebo	121.55	154.07	65	0.79	0.4330	0.05	-186.16	429.26

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Least Squares Means

Effect	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	1272.57	122.47	65	10.39	<.0001	0.05	1027.98	1517.16
TRTPN	2	1237.99	122.47	65	10.11	<.0001	0.05	993.40	1482.58
TRTPN	3	1265.96	122.47	65	10.34	<.0001	0.05	1021.37	1510.55
TRTPN	4	1072.39	122.47	65	8.76	<.0001	0.05	827.80	1316.98
TRTPN	5	808.04	122.47	65	6.60	<.0001	0.05	563.45	1052.63
TRTPN	6	1144.41	122.47	65	9.34	<.0001	0.05	899.82	1389.00

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	2	34.5817	154.07	65	0.22	0.8231	0.05	-273.12	342.29
TRTPN	1	3	6.6126	154.07	65	0.04	0.9659	0.05	-301.09	314.32
TRTPN	1	4	200.18	154.07	65	1.30	0.1984	0.05	-107.52	507.89
TRTPN	1	5	464.53	154.07	65	3.01	0.0037	0.05	156.83	772.24
TRTPN	1	6	128.16	153.73	65	0.83	0.4075	0.05	-178.85	435.18
TRTPN	2	3	-27.9691	154.07	65	-0.18	0.8565	0.05	-335.68	279.74
TRTPN	2	4	165.60	153.73	65	1.08	0.2854	0.05	-141.42	472.62
TRTPN	2	5	429.95	154.07	65	2.79	0.0069	0.05	122.24	737.66
TRTPN	2	6	93.5803	154.07	65	0.61	0.5457	0.05	-214.13	401.29
TRTPN	3	4	193.57	154.07	65	1.26	0.2135	0.05	-114.14	501.28
TRTPN	3	5	457.92	153.73	65	2.98	0.0041	0.05	150.90	764.94
TRTPN	3	6	121.55	154.07	65	0.79	0.4330	0.05	-186.16	429.26
TRTPN	4	5	264.35	154.07	65	1.72	0.0910	0.05	-43.3566	572.06

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=SEMAX

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	4	6	-72.0201	154.07	65	-0.47	0.6417	0.05	-379.73	235.69
TRTPN	5	6	-336.37	154.07	65	-2.18	0.0326	0.05	-644.08	-28.6636

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information

Class	Levels	Values
SUBJID	15	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017
TRTPN	6	1 2 3 4 5 6
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA

Dimensions

Covariance Parameters	2
Columns in X	19
Columns in Z	15
Subjects	1
Max Obs per Subject	90

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Number of Observations

Number of Observations Read	90
Number of Observations Used	90
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1214.80530325	
1	1	1149.08926784	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID(ARMCD)	454187
Residual	130654

Fit Statistics

-2 Res Log Likelihood	1149.1
AIC (Smaller is Better)	1153.1
AICC (Smaller is Better)	1153.3
BIC (Smaller is Better)	1154.5

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	65	3.21	0.0119
APERIOD	5	65	1.99	0.0923
ARMCD	5	9	0.56	0.7305

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	1
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	1
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Oxy 30 vs Placebo	64.4353	132.58	65	0.49	0.6286	0.05	-200.34	329.21
Oxy 60 vs Placebo	-258.67	132.58	65	-1.95	0.0554	0.05	-523.45	6.1076
Bel 300 vs Oxy 30	135.61	132.58	65	1.02	0.3102	0.05	-129.17	400.39
Bel 300 vs Oxy 60	458.72	132.58	65	3.46	0.0010	0.05	193.94	723.50
Bel 600 vs Oxy 30	-12.2582	132.28	65	-0.09	0.9265	0.05	-276.44	251.93
Bel 600 vs Oxy 60	310.85	132.58	65	2.34	0.0221	0.05	46.0695	575.63
Bel 900 vs Oxy 30	128.89	132.58	65	0.97	0.3346	0.05	-135.89	393.67
Bel 900 vs Oxy 60	451.99	132.28	65	3.42	0.0011	0.05	187.81	716.18
Bel 300 vs Placebo	200.05	132.28	65	1.51	0.1353	0.05	-64.1373	464.23
Bel 600 vs Placebo	52.1771	132.58	65	0.39	0.6952	0.05	-212.60	316.96
Bel 900 vs Placebo	193.32	132.58	65	1.46	0.1496	0.05	-71.4549	458.10

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Least Squares Means

Effect	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	1959.11	200.92	65	9.75	<.0001	0.05	1557.84	2360.38
TRTPN	2	1811.24	200.92	65	9.01	<.0001	0.05	1409.97	2212.51
TRTPN	3	1952.39	200.92	65	9.72	<.0001	0.05	1551.12	2353.66
TRTPN	4	1823.50	200.92	65	9.08	<.0001	0.05	1422.23	2224.77
TRTPN	5	1500.39	200.92	65	7.47	<.0001	0.05	1099.12	1901.66
TRTPN	6	1759.06	200.92	65	8.75	<.0001	0.05	1357.79	2160.34

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	2	147.87	132.58	65	1.12	0.2688	0.05	-116.91	412.65
TRTPN	1	3	6.7232	132.58	65	0.05	0.9597	0.05	-258.05	271.50
TRTPN	1	4	135.61	132.58	65	1.02	0.3102	0.05	-129.17	400.39
TRTPN	1	5	458.72	132.58	65	3.46	0.0010	0.05	193.94	723.50
TRTPN	1	6	200.05	132.28	65	1.51	0.1353	0.05	-64.1373	464.23
TRTPN	2	3	-141.15	132.58	65	-1.06	0.2910	0.05	-405.92	123.63
TRTPN	2	4	-12.2582	132.28	65	-0.09	0.9265	0.05	-276.44	251.93
TRTPN	2	5	310.85	132.58	65	2.34	0.0221	0.05	46.0695	575.63
TRTPN	2	6	52.1771	132.58	65	0.39	0.6952	0.05	-212.60	316.96
TRTPN	3	4	128.89	132.58	65	0.97	0.3346	0.05	-135.89	393.67
TRTPN	3	5	451.99	132.28	65	3.42	0.0011	0.05	187.81	716.18
TRTPN	3	6	193.32	132.58	65	1.46	0.1496	0.05	-71.4549	458.10
TRTPN	4	5	323.11	132.58	65	2.44	0.0176	0.05	58.3277	587.88

Appendix 16.1.9.2.1
Statistical Methods and Analysis Output Supporting Table 14.2.2
Supporting Table 14.2.2

The Mixed Procedure

Parameter Code=TVEMEMAX

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	4	6	64.4353	132.58	65	0.49	0.6286	0.05	-200.34	329.21
TRTPN	5	6	-258.67	132.58	65	-1.95	0.0554	0.05	-523.45	6.1076

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information

Class	Levels	Values
SUBJID	16	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017 1018
TRTPN	6	1 2 3 4 5 6
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA

Dimensions

Covariance Parameters	2
Columns in X	19
Columns in Z	16
Subjects	1
Max Obs per Subject	93

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Number of Observations

Number of Observations Read	93
Number of Observations Used	93
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	445.33349796	
1	2	425.58981336	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID(ARMCD)	5.7636
Residual	6.9739

Fit Statistics

-2 Res Log Likelihood	425.6
AIC (Smaller is Better)	429.6
AICC (Smaller is Better)	429.8
BIC (Smaller is Better)	431.1

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	67	3.46	0.0077
APERIOD	5	67	0.49	0.7812
ARMCD	5	10	0.76	0.5997

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	1
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	1
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Oxy 30 vs Placebo	1.3593	0.9559	67	1.42	0.1597	0.05	-0.5486	3.2672
Oxy 60 vs Placebo	2.7012	0.9375	67	2.88	0.0053	0.05	0.8298	4.5725
Bel 300 vs Oxy 30	-2.3356	0.9686	67	-2.41	0.0186	0.05	-4.2688	-0.4024
Bel 300 vs Oxy 60	-3.6775	0.9558	67	-3.85	0.0003	0.05	-5.5853	-1.7696
Bel 600 vs Oxy 30	-0.2433	0.9563	67	-0.25	0.7999	0.05	-2.1521	1.6655
Bel 600 vs Oxy 60	-1.5852	0.9375	67	-1.69	0.0955	0.05	-3.4564	0.2860
Bel 900 vs Oxy 30	-0.3133	0.9685	67	-0.32	0.7473	0.05	-2.2464	1.6198
Bel 900 vs Oxy 60	-1.6552	0.9563	67	-1.73	0.0881	0.05	-3.5639	0.2535
Bel 300 vs Placebo	-0.9763	0.9553	67	-1.02	0.3105	0.05	-2.8832	0.9305
Bel 600 vs Placebo	1.1159	0.9356	67	1.19	0.2372	0.05	-0.7515	2.9834
Bel 900 vs Placebo	1.0460	0.9559	67	1.09	0.2778	0.05	-0.8620	2.9539

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Least Squares Means

Effect	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	40.7846	0.9218	67	44.24	<.0001	0.1	39.2471	42.3220
TRTPN	2	42.8768	0.9025	67	47.51	<.0001	0.1	41.3715	44.3822
TRTPN	3	42.8069	0.9223	67	46.41	<.0001	0.1	41.2686	44.3451
TRTPN	4	43.1202	0.9223	67	46.75	<.0001	0.1	41.5819	44.6584
TRTPN	5	44.4621	0.9025	67	49.26	<.0001	0.1	42.9567	45.9674
TRTPN	6	41.7609	0.9025	67	46.27	<.0001	0.1	40.2556	43.2662

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	2	-2.0923	0.9578	67	-2.18	0.0324	0.1	-3.6898	-0.4948
TRTPN	1	3	-2.0223	0.9684	67	-2.09	0.0406	0.1	-3.6375	-0.4071
TRTPN	1	4	-2.3356	0.9686	67	-2.41	0.0186	0.1	-3.9511	-0.7201
TRTPN	1	5	-3.6775	0.9558	67	-3.85	0.0003	0.1	-5.2717	-2.0832
TRTPN	1	6	-0.9763	0.9553	67	-1.02	0.3105	0.1	-2.5697	0.6171
TRTPN	2	3	0.06998	0.9564	67	0.07	0.9419	0.1	-1.5253	1.6652
TRTPN	2	4	-0.2433	0.9563	67	-0.25	0.7999	0.1	-1.8384	1.3517
TRTPN	2	5	-1.5852	0.9375	67	-1.69	0.0955	0.1	-3.1488	-0.02161
TRTPN	2	6	1.1159	0.9356	67	1.19	0.2372	0.1	-0.4445	2.6764
TRTPN	3	4	-0.3133	0.9685	67	-0.32	0.7473	0.1	-1.9286	1.3020
TRTPN	3	5	-1.6552	0.9563	67	-1.73	0.0881	0.1	-3.2502	-0.06020
TRTPN	3	6	1.0460	0.9559	67	1.09	0.2778	0.1	-0.5483	2.6403
TRTPN	4	5	-1.3419	0.9563	67	-1.40	0.1652	0.1	-2.9369	0.2531

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=ETCOEMAX

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	4	6	1.3593	0.9559	67	1.42	0.1597	0.1	-0.2350	2.9536
TRTPN	5	6	2.7012	0.9375	67	2.88	0.0053	0.1	1.1374	4.2649

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information

Class	Levels	Values
SUBJID	16	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017 1018
TRTPN	6	1 2 3 4 5 6
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA

Dimensions

Covariance Parameters	2
Columns in X	19
Columns in Z	16
Subjects	1
Max Obs per Subject	93

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Number of Observations

Number of Observations Read	93
Number of Observations Used	93
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1601.99363318	
1	2	1591.96490482	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID(ARMCD)	12903876
Residual	28030184

Fit Statistics

-2 Res Log Likelihood	1592.0
AIC (Smaller is Better)	1596.0
AICC (Smaller is Better)	1596.1
BIC (Smaller is Better)	1597.5

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	67	3.06	0.0152
APERIOD	5	67	2.17	0.0677
ARMCD	5	10	0.88	0.5301

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	1
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	1
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Oxy 30 vs Placebo	-799.96	1915.28	67	-0.42	0.6775	0.05	-4622.87	3022.94
Oxy 60 vs Placebo	-5189.06	1879.60	67	-2.76	0.0074	0.05	-8940.75	-1437.38
Bel 300 vs Oxy 30	2034.96	1941.78	67	1.05	0.2984	0.05	-1840.84	5910.76
Bel 300 vs Oxy 60	6424.06	1915.22	67	3.35	0.0013	0.05	2601.26	10247
Bel 600 vs Oxy 30	736.00	1916.03	67	0.38	0.7021	0.05	-3088.41	4560.41
Bel 600 vs Oxy 60	5125.10	1879.45	67	2.73	0.0082	0.05	1373.69	8876.51
Bel 900 vs Oxy 30	1748.48	1941.60	67	0.90	0.3711	0.05	-2126.98	5623.93
Bel 900 vs Oxy 60	6137.58	1915.98	67	3.20	0.0021	0.05	2313.27	9961.88
Bel 300 vs Placebo	1234.99	1914.33	67	0.65	0.5210	0.05	-2586.03	5056.02
Bel 600 vs Placebo	-63.9639	1875.66	67	-0.03	0.9729	0.05	-3807.80	3679.88
Bel 900 vs Placebo	948.51	1915.28	67	0.50	0.6221	0.05	-2874.40	4771.42

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Least Squares Means

Effect	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	23560	1657.28	67	14.22	<.0001	0.1	20795	26324
TRTPN	2	22261	1615.19	67	13.78	<.0001	0.1	19567	24955
TRTPN	3	23273	1658.19	67	14.04	<.0001	0.1	20507	26039
TRTPN	4	21525	1658.19	67	12.98	<.0001	0.1	18759	24290
TRTPN	5	17136	1615.17	67	10.61	<.0001	0.1	14442	19830
TRTPN	6	22325	1615.11	67	13.82	<.0001	0.1	19631	25019

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	2	1298.96	1919.14	67	0.68	0.5008	0.1	-1902.01	4499.93
TRTPN	1	3	286.48	1941.50	67	0.15	0.8831	0.1	-2951.78	3524.74
TRTPN	1	4	2034.96	1941.78	67	1.05	0.2984	0.1	-1203.76	5273.68
TRTPN	1	5	6424.06	1915.22	67	3.35	0.0013	0.1	3229.63	9618.49
TRTPN	1	6	1234.99	1914.33	67	0.65	0.5210	0.1	-1957.96	4427.94
TRTPN	2	3	-1012.48	1916.29	67	-0.53	0.5990	0.1	-4208.68	2183.73
TRTPN	2	4	736.00	1916.03	67	0.38	0.7021	0.1	-2459.77	3931.77
TRTPN	2	5	5125.10	1879.45	67	2.73	0.0082	0.1	1990.33	8259.87
TRTPN	2	6	-63.9639	1875.66	67	-0.03	0.9729	0.1	-3192.41	3064.49
TRTPN	3	4	1748.48	1941.60	67	0.90	0.3711	0.1	-1489.95	4986.91
TRTPN	3	5	6137.58	1915.98	67	3.20	0.0021	0.1	2941.89	9333.26
TRTPN	3	6	948.51	1915.28	67	0.50	0.6221	0.1	-2246.01	4143.04
TRTPN	4	5	4389.10	1915.97	67	2.29	0.0251	0.1	1193.41	7584.79

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=MVMIEMAX

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	4	6	-799.96	1915.28	67	-0.42	0.6775	0.1	-3994.48	2394.55
TRTPN	5	6	-5189.06	1879.60	67	-2.76	0.0074	0.1	-8324.07	-2054.06

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information

Class	Levels	Values
SUBJID	16	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017 1018
TRTPN	6	1 2 3 4 5 6
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA

Dimensions

Covariance Parameters	2
Columns in X	19
Columns in Z	16
Subjects	1
Max Obs per Subject	93

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Number of Observations	
Number of Observations Read	93
Number of Observations Used	93
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	693.50873069	
1	2	683.88329081	0.00000004
2	1	683.88327887	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID(ARMCD)	94.1104
Residual	212.55

Fit Statistics	
-2 Res Log Likelihood	683.9
AIC (Smaller is Better)	687.9
AICC (Smaller is Better)	688.0
BIC (Smaller is Better)	689.4

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	67	2.58	0.0339
APERIOD	5	67	2.60	0.0327
ARMCD	5	10	0.62	0.6898

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	1
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	1
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Oxy 30 vs Placebo	0.2197	5.2738	67	0.04	0.9669	0.05	-10.3069	10.7464
Oxy 60 vs Placebo	-12.9112	5.1758	67	-2.49	0.0151	0.05	-23.2422	-2.5803
Bel 300 vs Oxy 30	2.8091	5.3470	67	0.53	0.6011	0.05	-7.8636	13.4818
Bel 300 vs Oxy 60	15.9401	5.2737	67	3.02	0.0035	0.05	5.4138	26.4664
Bel 600 vs Oxy 30	0.8329	5.2759	67	0.16	0.8750	0.05	-9.6978	11.3636
Bel 600 vs Oxy 60	13.9639	5.1754	67	2.70	0.0088	0.05	3.6337	24.2941
Bel 900 vs Oxy 30	2.0449	5.3465	67	0.38	0.7033	0.05	-8.6269	12.7166
Bel 900 vs Oxy 60	15.1758	5.2757	67	2.88	0.0054	0.05	4.6454	25.7063
Bel 300 vs Placebo	3.0289	5.2713	67	0.57	0.5675	0.05	-7.4926	13.5504
Bel 600 vs Placebo	1.0527	5.1650	67	0.20	0.8391	0.05	-9.2567	11.3620
Bel 900 vs Placebo	2.2646	5.2738	67	0.43	0.6690	0.05	-8.2620	12.7912

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Least Squares Means

Effect	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	61.5830	4.5368	67	13.57	<.0001	0.1	54.0160	69.1499
TRTPN	2	59.6068	4.4204	67	13.48	<.0001	0.1	52.2339	66.9796
TRTPN	3	60.8187	4.5393	67	13.40	<.0001	0.1	53.2476	68.3899
TRTPN	4	58.7739	4.5393	67	12.95	<.0001	0.1	51.2027	66.3450
TRTPN	5	45.6429	4.4204	67	10.33	<.0001	0.1	38.2701	53.0157
TRTPN	6	58.5541	4.4202	67	13.25	<.0001	0.1	51.1816	65.9266

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	2	1.9762	5.2845	67	0.37	0.7096	0.1	-6.8379	10.7903
TRTPN	1	3	0.7643	5.3463	67	0.14	0.8868	0.1	-8.1529	9.6814
TRTPN	1	4	2.8091	5.3470	67	0.53	0.6011	0.1	-6.1093	11.7275
TRTPN	1	5	15.9401	5.2737	67	3.02	0.0035	0.1	7.1440	24.7362
TRTPN	1	6	3.0289	5.2713	67	0.57	0.5675	0.1	-5.7632	11.8209
TRTPN	2	3	-1.2120	5.2766	67	-0.23	0.8190	0.1	-10.0129	7.5890
TRTPN	2	4	0.8329	5.2759	67	0.16	0.8750	0.1	-7.9668	9.6326
TRTPN	2	5	13.9639	5.1754	67	2.70	0.0088	0.1	5.3317	22.5960
TRTPN	2	6	1.0527	5.1650	67	0.20	0.8391	0.1	-7.5621	9.6674
TRTPN	3	4	2.0449	5.3465	67	0.38	0.7033	0.1	-6.8727	10.9624
TRTPN	3	5	15.1758	5.2757	67	2.88	0.0054	0.1	6.3764	23.9753
TRTPN	3	6	2.2646	5.2738	67	0.43	0.6690	0.1	-6.5317	11.0609
TRTPN	4	5	13.1310	5.2757	67	2.49	0.0153	0.1	4.3315	21.9305

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=PEFMEMAX

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	4	6	0.2197	5.2738	67	0.04	0.9669	0.1	-8.5766	9.0161
TRTPN	5	6	-12.9112	5.1758	67	-2.49	0.0151	0.1	-21.5440	-4.2785

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information

Class	Levels	Values
SUBJID	16	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017 1018
TRTPN	6	1 2 3 4 5 6
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA

Dimensions

Covariance Parameters	2
Columns in X	19
Columns in Z	16
Subjects	1
Max Obs per Subject	93

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Number of Observations

Number of Observations Read	93
Number of Observations Used	93
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1021.29677444	
1	2	1011.48017988	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID(ARMCD)	6773.79
Residual	14934

Fit Statistics

-2 Res Log Likelihood	1011.5
AIC (Smaller is Better)	1015.5
AICC (Smaller is Better)	1015.6
BIC (Smaller is Better)	1017.0

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	67	4.01	0.0030
APERIOD	5	67	2.31	0.0537
ARMCD	5	10	1.12	0.4076

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	1
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	1
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Oxy 30 vs Placebo	-21.2343	44.2084	67	-0.48	0.6326	0.05	-109.47	67.0060
Oxy 60 vs Placebo	-131.81	43.3855	67	-3.04	0.0034	0.05	-218.41	-45.2147
Bel 300 vs Oxy 30	64.6649	44.8207	67	1.44	0.1538	0.05	-24.7977	154.13
Bel 300 vs Oxy 60	175.24	44.2072	67	3.96	0.0002	0.05	87.0052	263.48
Bel 600 vs Oxy 30	14.7699	44.2257	67	0.33	0.7394	0.05	-73.5049	103.04
Bel 600 vs Oxy 60	125.35	43.3822	67	2.89	0.0052	0.05	38.7567	211.94
Bel 900 vs Oxy 30	50.0157	44.8168	67	1.12	0.2684	0.05	-39.4390	139.47
Bel 900 vs Oxy 60	160.59	44.2245	67	3.63	0.0005	0.05	72.3214	248.87
Bel 300 vs Placebo	43.4306	44.1868	67	0.98	0.3292	0.05	-44.7665	131.63
Bel 600 vs Placebo	-6.4645	43.2947	67	-0.15	0.8818	0.05	-92.8811	79.9522
Bel 900 vs Placebo	28.7813	44.2085	67	0.65	0.5172	0.05	-59.4592	117.02

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Least Squares Means

Effect	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	582.53	38.1672	67	15.26	<.0001	0.1	518.87	646.19
TRTPN	2	532.64	37.1942	67	14.32	<.0001	0.1	470.60	594.67
TRTPN	3	567.88	38.1883	67	14.87	<.0001	0.1	504.19	631.58
TRTPN	4	517.87	38.1882	67	13.56	<.0001	0.1	454.17	581.56
TRTPN	5	407.29	37.1938	67	10.95	<.0001	0.1	345.25	469.33
TRTPN	6	539.10	37.1923	67	14.49	<.0001	0.1	477.07	601.14

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	2	49.8950	44.2977	67	1.13	0.2640	0.1	-23.9897	123.78
TRTPN	1	3	14.6493	44.8145	67	0.33	0.7448	0.1	-60.0975	89.3960
TRTPN	1	4	64.6649	44.8207	67	1.44	0.1538	0.1	-10.0923	139.42
TRTPN	1	5	175.24	44.2072	67	3.96	0.0002	0.1	101.51	248.98
TRTPN	1	6	43.4306	44.1868	67	0.98	0.3292	0.1	-30.2692	117.13
TRTPN	2	3	-35.2458	44.2317	67	-0.80	0.4284	0.1	-109.02	38.5290
TRTPN	2	4	14.7699	44.2257	67	0.33	0.7394	0.1	-58.9948	88.5345
TRTPN	2	5	125.35	43.3822	67	2.89	0.0052	0.1	52.9901	197.71
TRTPN	2	6	-6.4645	43.2947	67	-0.15	0.8818	0.1	-78.6764	65.7475
TRTPN	3	4	50.0157	44.8168	67	1.12	0.2684	0.1	-24.7350	124.77
TRTPN	3	5	160.59	44.2245	67	3.63	0.0005	0.1	86.8311	234.36
TRTPN	3	6	28.7813	44.2085	67	0.65	0.5172	0.1	-44.9547	102.52
TRTPN	4	5	110.58	44.2244	67	2.50	0.0149	0.1	36.8155	184.34

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=REMAX

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	4	6	-21.2343	44.2084	67	-0.48	0.6326	0.1	-94.9702	52.5016
TRTPN	5	6	-131.81	43.3855	67	-3.04	0.0034	0.1	-204.18	-59.4492

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information

Class	Levels	Values
SUBJID	16	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017 1018
TRTPN	6	1 2 3 4 5 6
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA

Dimensions

Covariance Parameters	2
Columns in X	19
Columns in Z	16
Subjects	1
Max Obs per Subject	93

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Number of Observations

Number of Observations Read	93
Number of Observations Used	93
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	462.41208316	
1	3	434.25316146	0.00000768
2	1	434.25201500	0.00000001

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID(ARMCD)	8.5079
Residual	7.5427

Fit Statistics

-2 Res Log Likelihood	434.3
AIC (Smaller is Better)	438.3
AICC (Smaller is Better)	438.4
BIC (Smaller is Better)	439.8

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	67	1.08	0.3818
APERIOD	5	67	1.12	0.3558
ARMCD	5	10	0.81	0.5698

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	1
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	1
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Oxy 30 vs Placebo	-1.6707	0.9943	67	-1.68	0.0976	0.05	-3.6554	0.3140
Oxy 60 vs Placebo	-2.1015	0.9750	67	-2.16	0.0347	0.05	-4.0476	-0.1553
Bel 300 vs Oxy 30	0.4163	1.0073	67	0.41	0.6807	0.05	-1.5943	2.4268
Bel 300 vs Oxy 60	0.8470	0.9943	67	0.85	0.3973	0.05	-1.1376	2.8316
Bel 600 vs Oxy 30	0.4418	0.9948	67	0.44	0.6584	0.05	-1.5438	2.4275
Bel 600 vs Oxy 60	0.8726	0.9749	67	0.89	0.3740	0.05	-1.0734	2.8186
Bel 900 vs Oxy 30	0.05551	1.0072	67	0.06	0.9562	0.05	-1.9548	2.0659
Bel 900 vs Oxy 60	0.4862	0.9948	67	0.49	0.6266	0.05	-1.4993	2.4718
Bel 300 vs Placebo	-1.2544	0.9937	67	-1.26	0.2112	0.05	-3.2379	0.7291
Bel 600 vs Placebo	-1.2289	0.9730	67	-1.26	0.2110	0.05	-3.1710	0.7132
Bel 900 vs Placebo	-1.6152	0.9943	67	-1.62	0.1090	0.05	-3.5999	0.3695

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Least Squares Means

Effect	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	15.4944	1.0329	67	15.00	<.0001	0.1	13.7716	17.2171
TRTPN	2	15.5199	1.0141	67	15.30	<.0001	0.1	13.8285	17.2114
TRTPN	3	15.1336	1.0334	67	14.64	<.0001	0.1	13.4100	16.8572
TRTPN	4	15.0781	1.0334	67	14.59	<.0001	0.1	13.3545	16.8017
TRTPN	5	14.6473	1.0141	67	14.44	<.0001	0.1	12.9559	16.3388
TRTPN	6	16.7488	1.0141	67	16.52	<.0001	0.1	15.0574	18.4402

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	2	-0.02556	0.9963	67	-0.03	0.9796	0.1	-1.6873	1.6362
TRTPN	1	3	0.3608	1.0071	67	0.36	0.7213	0.1	-1.3191	2.0406
TRTPN	1	4	0.4163	1.0073	67	0.41	0.6807	0.1	-1.2638	2.0963
TRTPN	1	5	0.8470	0.9943	67	0.85	0.3973	0.1	-0.8114	2.5054
TRTPN	1	6	-1.2544	0.9937	67	-1.26	0.2112	0.1	-2.9119	0.4030
TRTPN	2	3	0.3863	0.9950	67	0.39	0.6990	0.1	-1.2732	2.0458
TRTPN	2	4	0.4418	0.9948	67	0.44	0.6584	0.1	-1.2174	2.1011
TRTPN	2	5	0.8726	0.9749	67	0.89	0.3740	0.1	-0.7536	2.4987
TRTPN	2	6	-1.2289	0.9730	67	-1.26	0.2110	0.1	-2.8517	0.3940
TRTPN	3	4	0.05551	1.0072	67	0.06	0.9562	0.1	-1.6244	1.7354
TRTPN	3	5	0.4862	0.9948	67	0.49	0.6266	0.1	-1.1730	2.1455
TRTPN	3	6	-1.6152	0.9943	67	-1.62	0.1090	0.1	-3.2737	0.04324
TRTPN	4	5	0.4307	0.9948	67	0.43	0.6664	0.1	-1.2285	2.0900

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=RRSPEMAX

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	4	6	-1.6707	0.9943	67	-1.68	0.0976	0.1	-3.3292	-0.01227
TRTPN	5	6	-2.1015	0.9750	67	-2.16	0.0347	0.1	-3.7277	-0.4752

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information

Class	Levels	Values
SUBJID	16	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017 1018
TRTPN	6	1 2 3 4 5 6
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA

Dimensions

Covariance Parameters	2
Columns in X	19
Columns in Z	16
Subjects	1
Max Obs per Subject	93

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Number of Observations

Number of Observations Read	93
Number of Observations Used	93
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1200.55113258	
1	2	1196.44710417	0.00000001
2	1	1196.44709777	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID(ARMCD)	41275
Residual	174256

Fit Statistics

-2 Res Log Likelihood	1196.4
AIC (Smaller is Better)	1200.4
AICC (Smaller is Better)	1200.6
BIC (Smaller is Better)	1202.0

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	67	3.07	0.0149
APERIOD	5	67	3.41	0.0083
ARMCD	5	10	1.21	0.3725

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	1
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	1
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		
ARMCD		CADBFE		
ARMCD		DCFAEB		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		EFBDAC		
ARMCD		FDECBA		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Oxy 30 vs Placebo	-100.13	150.90	67	-0.66	0.5093	0.05	-401.34	201.08
Oxy 60 vs Placebo	-379.92	148.20	67	-2.56	0.0126	0.05	-675.72	-84.1134
Bel 300 vs Oxy 30	202.07	153.10	67	1.32	0.1914	0.05	-103.52	507.66
Bel 300 vs Oxy 60	481.86	150.90	67	3.19	0.0021	0.05	180.66	783.06
Bel 600 vs Oxy 30	173.86	150.95	67	1.15	0.2535	0.05	-127.43	475.16
Bel 600 vs Oxy 60	453.65	148.19	67	3.06	0.0032	0.05	157.87	749.44
Bel 900 vs Oxy 30	191.81	153.09	67	1.25	0.2146	0.05	-113.76	497.37
Bel 900 vs Oxy 60	471.60	150.95	67	3.12	0.0026	0.05	170.31	772.89
Bel 300 vs Placebo	101.94	150.84	67	0.68	0.5015	0.05	-199.15	403.03
Bel 600 vs Placebo	73.7326	147.89	67	0.50	0.6197	0.05	-221.45	368.92
Bel 900 vs Placebo	91.6771	150.90	67	0.61	0.5456	0.05	-209.53	392.88

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Least Squares Means

Effect	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	1281.33	120.51	67	10.63	<.0001	0.1	1080.33	1482.32
TRTPN	2	1253.12	117.02	67	10.71	<.0001	0.1	1057.94	1448.30
TRTPN	3	1271.06	120.57	67	10.54	<.0001	0.1	1069.97	1472.16
TRTPN	4	1079.26	120.57	67	8.95	<.0001	0.1	878.16	1280.36
TRTPN	5	799.47	117.02	67	6.83	<.0001	0.1	604.29	994.65
TRTPN	6	1179.39	117.02	67	10.08	<.0001	0.1	984.22	1374.56

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	2	28.2077	151.21	67	0.19	0.8526	0.1	-224.00	280.41
TRTPN	1	3	10.2632	153.08	67	0.07	0.9467	0.1	-245.06	265.59
TRTPN	1	4	202.07	153.10	67	1.32	0.1914	0.1	-53.2914	457.43
TRTPN	1	5	481.86	150.90	67	3.19	0.0021	0.1	230.17	733.55
TRTPN	1	6	101.94	150.84	67	0.68	0.5015	0.1	-149.66	353.54
TRTPN	2	3	-17.9445	150.97	67	-0.12	0.9057	0.1	-269.75	233.86
TRTPN	2	4	173.86	150.95	67	1.15	0.2535	0.1	-77.9097	425.63
TRTPN	2	5	453.65	148.19	67	3.06	0.0032	0.1	206.49	700.82
TRTPN	2	6	73.7326	147.89	67	0.50	0.6197	0.1	-172.93	320.40
TRTPN	3	4	191.81	153.09	67	1.25	0.2146	0.1	-63.5327	447.14
TRTPN	3	5	471.60	150.95	67	3.12	0.0026	0.1	219.83	723.36
TRTPN	3	6	91.6771	150.90	67	0.61	0.5456	0.1	-160.02	343.37
TRTPN	4	5	279.79	150.95	67	1.85	0.0682	0.1	28.0255	531.56

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=SEMAX

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	4	6	-100.13	150.90	67	-0.66	0.5093	0.1	-351.82	151.57
TRTPN	5	6	-379.92	148.20	67	-2.56	0.0126	0.1	-627.10	-132.74

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information

Class	Levels	Values
SUBJID	16	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017 1018
TRTPN	6	1 2 3 4 5 6
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA

Dimensions

Covariance Parameters	2
Columns in X	19
Columns in Z	16
Subjects	1
Max Obs per Subject	93

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Number of Observations

Number of Observations Read	93
Number of Observations Used	93
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1262.49257037	
1	3	1199.66035259	0.00000852
2	1	1199.65567545	0.00000003
3	1	1199.65566003	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID(ARMCD)	414683
Residual	139616

Fit Statistics

-2 Res Log Likelihood	1199.7
AIC (Smaller is Better)	1203.7
AICC (Smaller is Better)	1203.8
BIC (Smaller is Better)	1205.2

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	67	2.55	0.0361
APERIOD	5	67	2.30	0.0541
ARMCD	5	10	0.58	0.7139

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	1
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Oxy 30 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		CADBFE		
ARMCD		DCFAEB		
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	1
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Oxy 60 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		CADBFE		
ARMCD		DCFAEB		
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 300 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		CADBFE		
ARMCD		DCFAEB		
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 300 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		CADBFE		
ARMCD		DCFAEB		
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 600 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		CADBFE		
ARMCD		DCFAEB		
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 600 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		CADBFE		
ARMCD		DCFAEB		
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	-1
TRTPN			5	
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 900 vs Oxy 30

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		CADBFE		
ARMCD		DCFAEB		
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	-1
TRTPN			6	
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 900 vs Oxy 60

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		CADBFE		
ARMCD		DCFAEB		
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	1
TRTPN			2	
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 300 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		CADBFE		
ARMCD		DCFAEB		
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	1
TRTPN			3	
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 600 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		CADBFE		
ARMCD		DCFAEB		
ARMCD		EFBDAC		
ARMCD		FDECBA		

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
Intercept				
TRTPN			1	
TRTPN			2	
TRTPN			3	1
TRTPN			4	
TRTPN			5	
TRTPN			6	-1
APERIOD	P1			
APERIOD	P2			
APERIOD	P3			
APERIOD	P4			
APERIOD	P5			
APERIOD	P6			
ARMCD		ABCEDF		
ARMCD		BEAFCD		

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Coefficients for Bel 900 vs Placebo

Effect	APERIOD	Planned Arm Code	Planned Treatment (N)	Row1
ARMCD		CADBFE		
ARMCD		DCFAEB		
ARMCD		EFBDAC		
ARMCD		FDECBA		

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Oxy 30 vs Placebo	85.6321	135.35	67	0.63	0.5291	0.05	-184.52	355.79
Oxy 60 vs Placebo	-187.67	132.65	67	-1.41	0.1618	0.05	-452.45	77.1076
Bel 300 vs Oxy 30	134.18	137.04	67	0.98	0.3310	0.05	-139.36	407.72
Bel 300 vs Oxy 60	407.48	135.34	67	3.01	0.0037	0.05	137.34	677.63
Bel 600 vs Oxy 30	-38.2811	135.42	67	-0.28	0.7783	0.05	-308.59	232.03
Bel 600 vs Oxy 60	235.02	132.64	67	1.77	0.0810	0.05	-29.7354	499.78
Bel 900 vs Oxy 30	134.25	137.03	67	0.98	0.3308	0.05	-139.26	407.76
Bel 900 vs Oxy 60	407.55	135.42	67	3.01	0.0037	0.05	137.25	677.85
Bel 300 vs Placebo	219.81	135.26	67	1.63	0.1088	0.05	-50.1648	489.79
Bel 600 vs Placebo	47.3510	132.38	67	0.36	0.7217	0.05	-216.87	311.58
Bel 900 vs Placebo	219.88	135.35	67	1.62	0.1090	0.05	-50.2740	490.04

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Least Squares Means

Effect	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	1937.48	190.88	67	10.15	<.0001	0.1	1619.11	2255.84
TRTPN	2	1765.02	188.96	67	9.34	<.0001	0.1	1449.85	2080.19
TRTPN	3	1937.55	190.93	67	10.15	<.0001	0.1	1619.09	2256.01
TRTPN	4	1803.30	190.93	67	9.44	<.0001	0.1	1484.84	2121.76
TRTPN	5	1529.99	188.96	67	8.10	<.0001	0.1	1214.82	1845.16
TRTPN	6	1717.67	188.96	67	9.09	<.0001	0.1	1402.50	2032.83

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	1	2	172.46	135.62	67	1.27	0.2079	0.1	-53.7416	398.66
TRTPN	1	3	-0.06905	137.02	67	-0.00	0.9996	0.1	-228.61	228.47
TRTPN	1	4	134.18	137.04	67	0.98	0.3310	0.1	-94.3961	362.75
TRTPN	1	5	407.48	135.34	67	3.01	0.0037	0.1	181.74	633.22
TRTPN	1	6	219.81	135.26	67	1.63	0.1088	0.1	-5.7877	445.41
TRTPN	2	3	-172.53	135.44	67	-1.27	0.2071	0.1	-398.44	53.3775
TRTPN	2	4	-38.2811	135.42	67	-0.28	0.7783	0.1	-264.16	187.59
TRTPN	2	5	235.02	132.64	67	1.77	0.0810	0.1	13.7839	456.26
TRTPN	2	6	47.3510	132.38	67	0.36	0.7217	0.1	-173.44	268.14
TRTPN	3	4	134.25	137.03	67	0.98	0.3308	0.1	-94.3054	362.80
TRTPN	3	5	407.55	135.42	67	3.01	0.0037	0.1	181.68	633.42
TRTPN	3	6	219.88	135.35	67	1.62	0.1090	0.1	-5.8676	445.63
TRTPN	4	5	273.30	135.42	67	2.02	0.0476	0.1	47.4358	499.17

Appendix 16.1.9.2.2
Statistical Methods and Analysis Output Supporting Table 14.2.3
Supporting Table 14.2.3

The Mixed Procedure

Parameter Code=TVEMEMAX

Differences of Least Squares Means

Effect	Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN	4	6	85.6321	135.35	67	0.63	0.5291	0.1	-140.12	311.38
TRTPN	5	6	-187.67	132.65	67	-1.41	0.1618	0.1	-408.93	33.5848

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Compound Symmetry
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Between-Within

Class Level Information

Class	Levels	Values
SUBJID	15	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017
TRTPN	6	Bel300 Bel600 Bel900 Oxy30 Oxy60 Plac
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA
ATPTN	6	0 0.5 1 2 3 4

Dimensions

Covariance Parameters	2
Columns in X	55
Columns in Z	0
Subjects	15
Max Obs per Subject	36

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Number of Observations

Number of Observations Read	527
Number of Observations Used	527
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	9845.22756633	
1	2	9742.18466751	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
CS	SUBJID	12122276
Residual		26084275

Fit Statistics

-2 Res Log Likelihood	9742.2
AIC (Smaller is Better)	9746.2
AICC (Smaller is Better)	9746.2
BIC (Smaller is Better)	9747.6

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
1	103.04	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	70	7.48	<.0001
APERIOD	5	70	5.76	0.0002
ARMCD	5	9	0.87	0.5343
TRTPN*ATPTN	30	407	2.21	0.0003

Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	0	20100	1607.72	407	12.50	<.0001	0.05	16940	23261
TRTPN*ATPTN	Bel300	0.5	21760	1607.72	407	13.53	<.0001	0.05	18599	24920
TRTPN*ATPTN	Bel300	1	19847	1607.72	407	12.35	<.0001	0.05	16687	23008
TRTPN*ATPTN	Bel300	2	19992	1607.72	407	12.43	<.0001	0.05	16831	23152
TRTPN*ATPTN	Bel300	3	15579	1607.72	407	9.69	<.0001	0.05	12418	18739
TRTPN*ATPTN	Bel300	4	16134	1607.72	407	10.04	<.0001	0.05	12974	19295
TRTPN*ATPTN	Bel600	0	19868	1646.63	407	12.07	<.0001	0.05	16631	23105
TRTPN*ATPTN	Bel600	0.5	20768	1646.63	407	12.61	<.0001	0.05	17531	24005
TRTPN*ATPTN	Bel600	1	19400	1607.76	407	12.07	<.0001	0.05	16240	22561
TRTPN*ATPTN	Bel600	2	17831	1607.76	407	11.09	<.0001	0.05	14670	20991

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel600	3	17241	1607.76	407	10.72	<.0001	0.05	14081	20402
TRTPN*ATPTN	Bel600	4	17258	1607.76	407	10.73	<.0001	0.05	14097	20418
TRTPN*ATPTN	Bel900	0	21445	1646.60	407	13.02	<.0001	0.05	18208	24682
TRTPN*ATPTN	Bel900	0.5	22890	1607.73	407	14.24	<.0001	0.05	19730	26051
TRTPN*ATPTN	Bel900	1	20071	1607.73	407	12.48	<.0001	0.05	16910	23231
TRTPN*ATPTN	Bel900	2	18313	1607.73	407	11.39	<.0001	0.05	15152	21473
TRTPN*ATPTN	Bel900	3	17633	1607.73	407	10.97	<.0001	0.05	14472	20793
TRTPN*ATPTN	Bel900	4	16584	1607.73	407	10.32	<.0001	0.05	13424	19745
TRTPN*ATPTN	Oxy30	0	20238	1691.50	407	11.96	<.0001	0.05	16913	23563
TRTPN*ATPTN	Oxy30	0.5	17966	1691.50	407	10.62	<.0001	0.05	14641	21291
TRTPN*ATPTN	Oxy30	1	16113	1646.66	407	9.79	<.0001	0.05	12876	19350
TRTPN*ATPTN	Oxy30	2	16969	1607.77	407	10.55	<.0001	0.05	13808	20129
TRTPN*ATPTN	Oxy30	3	18564	1607.77	407	11.55	<.0001	0.05	15403	21724
TRTPN*ATPTN	Oxy30	4	18784	1607.77	407	11.68	<.0001	0.05	15624	21945
TRTPN*ATPTN	Oxy60	0	19149	1692.33	407	11.32	<.0001	0.05	15823	22476
TRTPN*ATPTN	Oxy60	0.5	16780	1692.33	407	9.92	<.0001	0.05	13453	20106
TRTPN*ATPTN	Oxy60	1	14484	1648.55	407	8.79	<.0001	0.05	11243	17724
TRTPN*ATPTN	Oxy60	2	13262	1607.78	407	8.25	<.0001	0.05	10101	16422
TRTPN*ATPTN	Oxy60	3	13811	1607.78	407	8.59	<.0001	0.05	10650	16972
TRTPN*ATPTN	Oxy60	4	13931	1607.78	407	8.66	<.0001	0.05	10771	17092
TRTPN*ATPTN	Plac	0	18548	1607.72	407	11.54	<.0001	0.05	15388	21709
TRTPN*ATPTN	Plac	0.5	20129	1607.72	407	12.52	<.0001	0.05	16968	23289
TRTPN*ATPTN	Plac	1	21018	1607.72	407	13.07	<.0001	0.05	17857	24178
TRTPN*ATPTN	Plac	2	17212	1607.72	407	10.71	<.0001	0.05	14052	20373

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Plac	3	17014	1607.72	407	10.58	<.0001	0.05	13854	20175
TRTPN*ATPTN	Plac	4	18407	1607.72	407	11.45	<.0001	0.05	15247	21568

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	0	Bel300	0.5	-1659.32	1864.91	407	-0.89	0.3741	0.05	-5325.39	2006.74
TRTPN*ATPTN	Bel300	0	Bel300	1	252.85	1864.91	407	0.14	0.8922	0.05	-3413.21	3918.92
TRTPN*ATPTN	Bel300	0	Bel300	2	108.37	1864.91	407	0.06	0.9537	0.05	-3557.70	3774.43
TRTPN*ATPTN	Bel300	0	Bel300	3	4521.35	1864.91	407	2.42	0.0158	0.05	855.29	8187.42
TRTPN*ATPTN	Bel300	0	Bel300	4	3966.17	1864.91	407	2.13	0.0340	0.05	300.11	7632.24
TRTPN*ATPTN	Bel300	0	Bel600	0	232.42	1899.90	407	0.12	0.9027	0.05	-3502.42	3967.27
TRTPN*ATPTN	Bel300	0	Bel600	0.5	-668.08	1899.90	407	-0.35	0.7253	0.05	-4402.92	3066.77
TRTPN*ATPTN	Bel300	0	Bel600	1	699.98	1866.36	407	0.38	0.7078	0.05	-2968.93	4368.88
TRTPN*ATPTN	Bel300	0	Bel600	2	2269.65	1866.36	407	1.22	0.2247	0.05	-1399.26	5938.55
TRTPN*ATPTN	Bel300	0	Bel600	3	2858.87	1866.36	407	1.53	0.1264	0.05	-810.04	6527.77
TRTPN*ATPTN	Bel300	0	Bel600	4	2842.61	1866.36	407	1.52	0.1285	0.05	-826.30	6511.51
TRTPN*ATPTN	Bel300	0	Bel900	0	-1344.38	1899.87	407	-0.71	0.4796	0.05	-5079.16	2390.40
TRTPN*ATPTN	Bel300	0	Bel900	0.5	-2789.80	1866.33	407	-1.49	0.1357	0.05	-6458.65	879.04
TRTPN*ATPTN	Bel300	0	Bel900	1	29.6690	1866.33	407	0.02	0.9873	0.05	-3639.18	3698.51
TRTPN*ATPTN	Bel300	0	Bel900	2	1787.42	1866.33	407	0.96	0.3388	0.05	-1881.42	5456.27
TRTPN*ATPTN	Bel300	0	Bel900	3	2467.69	1866.33	407	1.32	0.1868	0.05	-1201.16	6136.53
TRTPN*ATPTN	Bel300	0	Bel900	4	3516.18	1866.33	407	1.88	0.0603	0.05	-152.67	7185.02

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	0	Oxy30	0	-137.82	1938.87	407	-0.07	0.9434	0.05	-3949.28	3673.64
TRTPN*ATPTN	Bel300	0	Oxy30	0.5	2134.33	1938.87	407	1.10	0.2716	0.05	-1677.13	5945.78
TRTPN*ATPTN	Bel300	0	Oxy30	1	3987.34	1899.93	407	2.10	0.0365	0.05	252.43	7722.24
TRTPN*ATPTN	Bel300	0	Oxy30	2	3131.59	1866.36	407	1.68	0.0941	0.05	-537.33	6800.51
TRTPN*ATPTN	Bel300	0	Oxy30	3	1536.75	1866.36	407	0.82	0.4108	0.05	-2132.16	5205.67
TRTPN*ATPTN	Bel300	0	Oxy30	4	1316.00	1866.36	407	0.71	0.4811	0.05	-2352.92	4984.92
TRTPN*ATPTN	Bel300	0	Oxy60	0	950.87	1939.56	407	0.49	0.6242	0.05	-2861.94	4763.68
TRTPN*ATPTN	Bel300	0	Oxy60	0.5	3320.72	1939.56	407	1.71	0.0876	0.05	-492.09	7133.53
TRTPN*ATPTN	Bel300	0	Oxy60	1	5616.58	1900.77	407	2.95	0.0033	0.05	1880.02	9353.14
TRTPN*ATPTN	Bel300	0	Oxy60	2	6838.81	1866.36	407	3.66	0.0003	0.05	3169.89	10508
TRTPN*ATPTN	Bel300	0	Oxy60	3	6289.34	1866.36	407	3.37	0.0008	0.05	2620.42	9958.26
TRTPN*ATPTN	Bel300	0	Oxy60	4	6169.20	1866.36	407	3.31	0.0010	0.05	2500.29	9838.12
TRTPN*ATPTN	Bel300	0	Plac	0	1552.01	1865.61	407	0.83	0.4059	0.05	-2115.42	5219.44
TRTPN*ATPTN	Bel300	0	Plac	0.5	-28.3753	1865.61	407	-0.02	0.9879	0.05	-3695.80	3639.05
TRTPN*ATPTN	Bel300	0	Plac	1	-917.63	1865.61	407	-0.49	0.6231	0.05	-4585.06	2749.79
TRTPN*ATPTN	Bel300	0	Plac	2	2887.83	1865.61	407	1.55	0.1224	0.05	-779.60	6555.26
TRTPN*ATPTN	Bel300	0	Plac	3	3085.85	1865.61	407	1.65	0.0989	0.05	-581.58	6753.28
TRTPN*ATPTN	Bel300	0	Plac	4	1693.01	1865.61	407	0.91	0.3647	0.05	-1974.42	5360.43
TRTPN*ATPTN	Bel300	0.5	Bel300	1	1912.18	1864.91	407	1.03	0.3058	0.05	-1753.89	5578.24
TRTPN*ATPTN	Bel300	0.5	Bel300	2	1767.69	1864.91	407	0.95	0.3438	0.05	-1898.38	5433.75
TRTPN*ATPTN	Bel300	0.5	Bel300	3	6180.67	1864.91	407	3.31	0.0010	0.05	2514.61	9846.74
TRTPN*ATPTN	Bel300	0.5	Bel300	4	5625.50	1864.91	407	3.02	0.0027	0.05	1959.43	9291.56
TRTPN*ATPTN	Bel300	0.5	Bel600	0	1891.74	1899.90	407	1.00	0.3200	0.05	-1843.10	5626.59
TRTPN*ATPTN	Bel300	0.5	Bel600	0.5	991.25	1899.90	407	0.52	0.6021	0.05	-2743.60	4726.09
TRTPN*ATPTN	Bel300	0.5	Bel600	1	2359.30	1866.36	407	1.26	0.2069	0.05	-1309.61	6028.20

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	0.5	Bel600	2	3928.97	1866.36	407	2.11	0.0359	0.05	260.07	7597.88
TRTPN*ATPTN	Bel300	0.5	Bel600	3	4518.19	1866.36	407	2.42	0.0159	0.05	849.28	8187.09
TRTPN*ATPTN	Bel300	0.5	Bel600	4	4501.93	1866.36	407	2.41	0.0163	0.05	833.02	8170.83
TRTPN*ATPTN	Bel300	0.5	Bel900	0	314.94	1899.87	407	0.17	0.8684	0.05	-3419.84	4049.73
TRTPN*ATPTN	Bel300	0.5	Bel900	0.5	-1130.48	1866.33	407	-0.61	0.5450	0.05	-4799.33	2538.36
TRTPN*ATPTN	Bel300	0.5	Bel900	1	1688.99	1866.33	407	0.90	0.3660	0.05	-1979.86	5357.84
TRTPN*ATPTN	Bel300	0.5	Bel900	2	3446.74	1866.33	407	1.85	0.0655	0.05	-222.10	7115.59
TRTPN*ATPTN	Bel300	0.5	Bel900	3	4127.01	1866.33	407	2.21	0.0276	0.05	458.16	7795.85
TRTPN*ATPTN	Bel300	0.5	Bel900	4	5175.50	1866.33	407	2.77	0.0058	0.05	1506.65	8844.34
TRTPN*ATPTN	Bel300	0.5	Oxy30	0	1521.50	1938.87	407	0.78	0.4331	0.05	-2289.96	5332.96
TRTPN*ATPTN	Bel300	0.5	Oxy30	0.5	3793.65	1938.87	407	1.96	0.0511	0.05	-17.8074	7605.10
TRTPN*ATPTN	Bel300	0.5	Oxy30	1	5646.66	1899.93	407	2.97	0.0031	0.05	1911.76	9381.56
TRTPN*ATPTN	Bel300	0.5	Oxy30	2	4790.91	1866.36	407	2.57	0.0106	0.05	1121.99	8459.83
TRTPN*ATPTN	Bel300	0.5	Oxy30	3	3196.07	1866.36	407	1.71	0.0876	0.05	-472.84	6864.99
TRTPN*ATPTN	Bel300	0.5	Oxy30	4	2975.32	1866.36	407	1.59	0.1117	0.05	-693.60	6644.24
TRTPN*ATPTN	Bel300	0.5	Oxy60	0	2610.19	1939.56	407	1.35	0.1791	0.05	-1202.62	6423.01
TRTPN*ATPTN	Bel300	0.5	Oxy60	0.5	4980.04	1939.56	407	2.57	0.0106	0.05	1167.23	8792.85
TRTPN*ATPTN	Bel300	0.5	Oxy60	1	7275.90	1900.77	407	3.83	0.0001	0.05	3539.34	11012
TRTPN*ATPTN	Bel300	0.5	Oxy60	2	8498.13	1866.36	407	4.55	<.0001	0.05	4829.22	12167
TRTPN*ATPTN	Bel300	0.5	Oxy60	3	7948.66	1866.36	407	4.26	<.0001	0.05	4279.74	11618
TRTPN*ATPTN	Bel300	0.5	Oxy60	4	7828.52	1866.36	407	4.19	<.0001	0.05	4159.61	11497
TRTPN*ATPTN	Bel300	0.5	Plac	0	3211.33	1865.61	407	1.72	0.0860	0.05	-456.10	6878.76
TRTPN*ATPTN	Bel300	0.5	Plac	0.5	1630.95	1865.61	407	0.87	0.3825	0.05	-2036.48	5298.37
TRTPN*ATPTN	Bel300	0.5	Plac	1	741.69	1865.61	407	0.40	0.6912	0.05	-2925.74	4409.12
TRTPN*ATPTN	Bel300	0.5	Plac	2	4547.15	1865.61	407	2.44	0.0152	0.05	879.72	8214.58

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	0.5	Plac	3	4745.17	1865.61	407	2.54	0.0113	0.05	1077.74	8412.60
TRTPN*ATPTN	Bel300	0.5	Plac	4	3352.33	1865.61	407	1.80	0.0731	0.05	-315.10	7019.76
TRTPN*ATPTN	Bel300	1	Bel300	2	-144.49	1864.91	407	-0.08	0.9383	0.05	-3810.56	3521.58
TRTPN*ATPTN	Bel300	1	Bel300	3	4268.50	1864.91	407	2.29	0.0226	0.05	602.43	7934.56
TRTPN*ATPTN	Bel300	1	Bel300	4	3713.32	1864.91	407	1.99	0.0471	0.05	47.2543	7379.39
TRTPN*ATPTN	Bel300	1	Bel600	0	-20.4327	1899.90	407	-0.01	0.9914	0.05	-3755.28	3714.41
TRTPN*ATPTN	Bel300	1	Bel600	0.5	-920.93	1899.90	407	-0.48	0.6281	0.05	-4655.78	2813.92
TRTPN*ATPTN	Bel300	1	Bel600	1	447.12	1866.36	407	0.24	0.8108	0.05	-3221.78	4116.03
TRTPN*ATPTN	Bel300	1	Bel600	2	2016.79	1866.36	407	1.08	0.2805	0.05	-1652.11	5685.70
TRTPN*ATPTN	Bel300	1	Bel600	3	2606.01	1866.36	407	1.40	0.1634	0.05	-1062.89	6274.92
TRTPN*ATPTN	Bel300	1	Bel600	4	2589.75	1866.36	407	1.39	0.1660	0.05	-1079.15	6258.66
TRTPN*ATPTN	Bel300	1	Bel900	0	-1597.23	1899.87	407	-0.84	0.4010	0.05	-5332.01	2137.55
TRTPN*ATPTN	Bel300	1	Bel900	0.5	-3042.66	1866.33	407	-1.63	0.1038	0.05	-6711.50	626.19
TRTPN*ATPTN	Bel300	1	Bel900	1	-223.19	1866.33	407	-0.12	0.9049	0.05	-3892.03	3445.66
TRTPN*ATPTN	Bel300	1	Bel900	2	1534.57	1866.33	407	0.82	0.4114	0.05	-2134.28	5203.41
TRTPN*ATPTN	Bel300	1	Bel900	3	2214.83	1866.33	407	1.19	0.2360	0.05	-1454.01	5883.68
TRTPN*ATPTN	Bel300	1	Bel900	4	3263.32	1866.33	407	1.75	0.0811	0.05	-405.52	6932.17
TRTPN*ATPTN	Bel300	1	Oxy30	0	-390.68	1938.87	407	-0.20	0.8404	0.05	-4202.13	3420.78
TRTPN*ATPTN	Bel300	1	Oxy30	0.5	1881.47	1938.87	407	0.97	0.3324	0.05	-1929.98	5692.93
TRTPN*ATPTN	Bel300	1	Oxy30	1	3734.48	1899.93	407	1.97	0.0500	0.05	-0.4199	7469.38
TRTPN*ATPTN	Bel300	1	Oxy30	2	2878.74	1866.36	407	1.54	0.1237	0.05	-790.18	6547.65
TRTPN*ATPTN	Bel300	1	Oxy30	3	1283.90	1866.36	407	0.69	0.4919	0.05	-2385.02	4952.82
TRTPN*ATPTN	Bel300	1	Oxy30	4	1063.15	1866.36	407	0.57	0.5692	0.05	-2605.77	4732.06
TRTPN*ATPTN	Bel300	1	Oxy60	0	698.02	1939.56	407	0.36	0.7191	0.05	-3114.79	4510.83
TRTPN*ATPTN	Bel300	1	Oxy60	0.5	3067.86	1939.56	407	1.58	0.1145	0.05	-744.95	6880.67

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	1	Oxy60	1	5363.73	1900.77	407	2.82	0.0050	0.05	1627.16	9100.29
TRTPN*ATPTN	Bel300	1	Oxy60	2	6585.96	1866.36	407	3.53	0.0005	0.05	2917.04	10255
TRTPN*ATPTN	Bel300	1	Oxy60	3	6036.48	1866.36	407	3.23	0.0013	0.05	2367.57	9705.40
TRTPN*ATPTN	Bel300	1	Oxy60	4	5916.35	1866.36	407	3.17	0.0016	0.05	2247.43	9585.27
TRTPN*ATPTN	Bel300	1	Plac	0	1299.16	1865.61	407	0.70	0.4866	0.05	-2368.27	4966.59
TRTPN*ATPTN	Bel300	1	Plac	0.5	-281.23	1865.61	407	-0.15	0.8803	0.05	-3948.66	3386.20
TRTPN*ATPTN	Bel300	1	Plac	1	-1170.49	1865.61	407	-0.63	0.5307	0.05	-4837.92	2496.94
TRTPN*ATPTN	Bel300	1	Plac	2	2634.97	1865.61	407	1.41	0.1586	0.05	-1032.46	6302.40
TRTPN*ATPTN	Bel300	1	Plac	3	2832.99	1865.61	407	1.52	0.1297	0.05	-834.43	6500.42
TRTPN*ATPTN	Bel300	1	Plac	4	1440.15	1865.61	407	0.77	0.4406	0.05	-2227.28	5107.58
TRTPN*ATPTN	Bel300	2	Bel300	3	4412.99	1864.91	407	2.37	0.0184	0.05	746.92	8079.05
TRTPN*ATPTN	Bel300	2	Bel300	4	3857.81	1864.91	407	2.07	0.0392	0.05	191.74	7523.88
TRTPN*ATPTN	Bel300	2	Bel600	0	124.06	1899.90	407	0.07	0.9480	0.05	-3610.79	3858.90
TRTPN*ATPTN	Bel300	2	Bel600	0.5	-776.44	1899.90	407	-0.41	0.6830	0.05	-4511.29	2958.41
TRTPN*ATPTN	Bel300	2	Bel600	1	591.61	1866.36	407	0.32	0.7514	0.05	-3077.29	4260.52
TRTPN*ATPTN	Bel300	2	Bel600	2	2161.28	1866.36	407	1.16	0.2475	0.05	-1507.62	5830.19
TRTPN*ATPTN	Bel300	2	Bel600	3	2750.50	1866.36	407	1.47	0.1413	0.05	-918.40	6419.41
TRTPN*ATPTN	Bel300	2	Bel600	4	2734.24	1866.36	407	1.47	0.1437	0.05	-934.66	6403.15
TRTPN*ATPTN	Bel300	2	Bel900	0	-1452.74	1899.87	407	-0.76	0.4449	0.05	-5187.53	2282.04
TRTPN*ATPTN	Bel300	2	Bel900	0.5	-2898.17	1866.33	407	-1.55	0.1212	0.05	-6567.01	770.68
TRTPN*ATPTN	Bel300	2	Bel900	1	-78.6961	1866.33	407	-0.04	0.9664	0.05	-3747.54	3590.15
TRTPN*ATPTN	Bel300	2	Bel900	2	1679.06	1866.33	407	0.90	0.3688	0.05	-1989.79	5347.90
TRTPN*ATPTN	Bel300	2	Bel900	3	2359.32	1866.33	407	1.26	0.2069	0.05	-1309.52	6028.17
TRTPN*ATPTN	Bel300	2	Bel900	4	3407.81	1866.33	407	1.83	0.0686	0.05	-261.03	7076.66
TRTPN*ATPTN	Bel300	2	Oxy30	0	-246.19	1938.87	407	-0.13	0.8990	0.05	-4057.64	3565.27

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	2	Oxy30	0.5	2025.96	1938.87	407	1.04	0.2967	0.05	-1785.49	5837.42
TRTPN*ATPTN	Bel300	2	Oxy30	1	3878.97	1899.93	407	2.04	0.0418	0.05	144.07	7613.87
TRTPN*ATPTN	Bel300	2	Oxy30	2	3023.23	1866.36	407	1.62	0.1060	0.05	-645.69	6692.14
TRTPN*ATPTN	Bel300	2	Oxy30	3	1428.39	1866.36	407	0.77	0.4445	0.05	-2240.53	5097.31
TRTPN*ATPTN	Bel300	2	Oxy30	4	1207.64	1866.36	407	0.65	0.5180	0.05	-2461.28	4876.55
TRTPN*ATPTN	Bel300	2	Oxy60	0	842.51	1939.56	407	0.43	0.6642	0.05	-2970.30	4655.32
TRTPN*ATPTN	Bel300	2	Oxy60	0.5	3212.35	1939.56	407	1.66	0.0984	0.05	-600.46	7025.16
TRTPN*ATPTN	Bel300	2	Oxy60	1	5508.22	1900.77	407	2.90	0.0040	0.05	1771.65	9244.78
TRTPN*ATPTN	Bel300	2	Oxy60	2	6730.45	1866.36	407	3.61	0.0003	0.05	3061.53	10399
TRTPN*ATPTN	Bel300	2	Oxy60	3	6180.97	1866.36	407	3.31	0.0010	0.05	2512.06	9849.89
TRTPN*ATPTN	Bel300	2	Oxy60	4	6060.84	1866.36	407	3.25	0.0013	0.05	2391.92	9729.76
TRTPN*ATPTN	Bel300	2	Plac	0	1443.65	1865.61	407	0.77	0.4395	0.05	-2223.78	5111.08
TRTPN*ATPTN	Bel300	2	Plac	0.5	-136.74	1865.61	407	-0.07	0.9416	0.05	-3804.17	3530.69
TRTPN*ATPTN	Bel300	2	Plac	1	-1026.00	1865.61	407	-0.55	0.5827	0.05	-4693.43	2641.43
TRTPN*ATPTN	Bel300	2	Plac	2	2779.46	1865.61	407	1.49	0.1370	0.05	-887.97	6446.89
TRTPN*ATPTN	Bel300	2	Plac	3	2977.48	1865.61	407	1.60	0.1113	0.05	-689.95	6644.91
TRTPN*ATPTN	Bel300	2	Plac	4	1584.64	1865.61	407	0.85	0.3962	0.05	-2082.79	5252.07
TRTPN*ATPTN	Bel300	3	Bel300	4	-555.18	1864.91	407	-0.30	0.7661	0.05	-4221.24	3110.89
TRTPN*ATPTN	Bel300	3	Bel600	0	-4288.93	1899.90	407	-2.26	0.0245	0.05	-8023.78	-554.08
TRTPN*ATPTN	Bel300	3	Bel600	0.5	-5189.43	1899.90	407	-2.73	0.0066	0.05	-8924.27	-1454.58
TRTPN*ATPTN	Bel300	3	Bel600	1	-3821.38	1866.36	407	-2.05	0.0413	0.05	-7490.28	-152.47
TRTPN*ATPTN	Bel300	3	Bel600	2	-2251.70	1866.36	407	-1.21	0.2283	0.05	-5920.61	1417.20
TRTPN*ATPTN	Bel300	3	Bel600	3	-1662.49	1866.36	407	-0.89	0.3736	0.05	-5331.39	2006.42
TRTPN*ATPTN	Bel300	3	Bel600	4	-1678.75	1866.36	407	-0.90	0.3689	0.05	-5347.65	1990.16
TRTPN*ATPTN	Bel300	3	Bel900	0	-5865.73	1899.87	407	-3.09	0.0022	0.05	-9600.51	-2130.95

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	3	Bel900	0.5	-7311.16	1866.33	407	-3.92	0.0001	0.05	-10980	-3642.31
TRTPN*ATPTN	Bel300	3	Bel900	1	-4491.68	1866.33	407	-2.41	0.0165	0.05	-8160.53	-822.84
TRTPN*ATPTN	Bel300	3	Bel900	2	-2733.93	1866.33	407	-1.46	0.1437	0.05	-6402.78	934.92
TRTPN*ATPTN	Bel300	3	Bel900	3	-2053.67	1866.33	407	-1.10	0.2718	0.05	-5722.51	1615.18
TRTPN*ATPTN	Bel300	3	Bel900	4	-1005.18	1866.33	407	-0.54	0.5905	0.05	-4674.02	2663.67
TRTPN*ATPTN	Bel300	3	Oxy30	0	-4659.17	1938.87	407	-2.40	0.0167	0.05	-8470.63	-847.72
TRTPN*ATPTN	Bel300	3	Oxy30	0.5	-2387.03	1938.87	407	-1.23	0.2190	0.05	-6198.48	1424.43
TRTPN*ATPTN	Bel300	3	Oxy30	1	-534.02	1899.93	407	-0.28	0.7788	0.05	-4268.92	3200.88
TRTPN*ATPTN	Bel300	3	Oxy30	2	-1389.76	1866.36	407	-0.74	0.4569	0.05	-5058.68	2279.16
TRTPN*ATPTN	Bel300	3	Oxy30	3	-2984.60	1866.36	407	-1.60	0.1106	0.05	-6653.52	684.32
TRTPN*ATPTN	Bel300	3	Oxy30	4	-3205.35	1866.36	407	-1.72	0.0867	0.05	-6874.27	463.57
TRTPN*ATPTN	Bel300	3	Oxy60	0	-3570.48	1939.56	407	-1.84	0.0664	0.05	-7383.29	242.33
TRTPN*ATPTN	Bel300	3	Oxy60	0.5	-1200.64	1939.56	407	-0.62	0.5362	0.05	-5013.45	2612.18
TRTPN*ATPTN	Bel300	3	Oxy60	1	1095.23	1900.77	407	0.58	0.5648	0.05	-2641.33	4831.79
TRTPN*ATPTN	Bel300	3	Oxy60	2	2317.46	1866.36	407	1.24	0.2151	0.05	-1351.46	5986.38
TRTPN*ATPTN	Bel300	3	Oxy60	3	1767.99	1866.36	407	0.95	0.3441	0.05	-1900.93	5436.90
TRTPN*ATPTN	Bel300	3	Oxy60	4	1647.85	1866.36	407	0.88	0.3778	0.05	-2021.07	5316.77
TRTPN*ATPTN	Bel300	3	Plac	0	-2969.34	1865.61	407	-1.59	0.1122	0.05	-6636.77	698.09
TRTPN*ATPTN	Bel300	3	Plac	0.5	-4549.73	1865.61	407	-2.44	0.0152	0.05	-8217.16	-882.30
TRTPN*ATPTN	Bel300	3	Plac	1	-5438.99	1865.61	407	-2.92	0.0037	0.05	-9106.42	-1771.56
TRTPN*ATPTN	Bel300	3	Plac	2	-1633.53	1865.61	407	-0.88	0.3818	0.05	-5300.95	2033.90
TRTPN*ATPTN	Bel300	3	Plac	3	-1435.50	1865.61	407	-0.77	0.4421	0.05	-5102.93	2231.93
TRTPN*ATPTN	Bel300	3	Plac	4	-2828.35	1865.61	407	-1.52	0.1303	0.05	-6495.78	839.08
TRTPN*ATPTN	Bel300	4	Bel600	0	-3733.75	1899.90	407	-1.97	0.0501	0.05	-7468.60	1.0934
TRTPN*ATPTN	Bel300	4	Bel600	0.5	-4634.25	1899.90	407	-2.44	0.0151	0.05	-8369.10	-899.40

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	4	Bel600	1	-3266.20	1866.36	407	-1.75	0.0809	0.05	-6935.10	402.71
TRTPN*ATPTN	Bel300	4	Bel600	2	-1696.53	1866.36	407	-0.91	0.3639	0.05	-5365.43	1972.38
TRTPN*ATPTN	Bel300	4	Bel600	3	-1107.31	1866.36	407	-0.59	0.5533	0.05	-4776.21	2561.60
TRTPN*ATPTN	Bel300	4	Bel600	4	-1123.57	1866.36	407	-0.60	0.5475	0.05	-4792.47	2545.34
TRTPN*ATPTN	Bel300	4	Bel900	0	-5310.55	1899.87	407	-2.80	0.0054	0.05	-9045.33	-1575.77
TRTPN*ATPTN	Bel300	4	Bel900	0.5	-6755.98	1866.33	407	-3.62	0.0003	0.05	-10425	-3087.13
TRTPN*ATPTN	Bel300	4	Bel900	1	-3936.51	1866.33	407	-2.11	0.0355	0.05	-7605.35	-267.66
TRTPN*ATPTN	Bel300	4	Bel900	2	-2178.75	1866.33	407	-1.17	0.2437	0.05	-5847.60	1490.09
TRTPN*ATPTN	Bel300	4	Bel900	3	-1498.49	1866.33	407	-0.80	0.4225	0.05	-5167.33	2170.36
TRTPN*ATPTN	Bel300	4	Bel900	4	-450.00	1866.33	407	-0.24	0.8096	0.05	-4118.84	3218.85
TRTPN*ATPTN	Bel300	4	Oxy30	0	-4104.00	1938.87	407	-2.12	0.0349	0.05	-7915.45	-292.54
TRTPN*ATPTN	Bel300	4	Oxy30	0.5	-1831.85	1938.87	407	-0.94	0.3453	0.05	-5643.30	1979.61
TRTPN*ATPTN	Bel300	4	Oxy30	1	21.1604	1899.93	407	0.01	0.9911	0.05	-3713.74	3756.06
TRTPN*ATPTN	Bel300	4	Oxy30	2	-834.58	1866.36	407	-0.45	0.6550	0.05	-4503.50	2834.33
TRTPN*ATPTN	Bel300	4	Oxy30	3	-2429.42	1866.36	407	-1.30	0.1938	0.05	-6098.34	1239.50
TRTPN*ATPTN	Bel300	4	Oxy30	4	-2650.17	1866.36	407	-1.42	0.1564	0.05	-6319.09	1018.74
TRTPN*ATPTN	Bel300	4	Oxy60	0	-3015.30	1939.56	407	-1.55	0.1208	0.05	-6828.11	797.51
TRTPN*ATPTN	Bel300	4	Oxy60	0.5	-645.46	1939.56	407	-0.33	0.7395	0.05	-4458.27	3167.35
TRTPN*ATPTN	Bel300	4	Oxy60	1	1650.41	1900.77	407	0.87	0.3858	0.05	-2086.16	5386.97
TRTPN*ATPTN	Bel300	4	Oxy60	2	2872.64	1866.36	407	1.54	0.1245	0.05	-796.28	6541.55
TRTPN*ATPTN	Bel300	4	Oxy60	3	2323.16	1866.36	407	1.24	0.2139	0.05	-1345.75	5992.08
TRTPN*ATPTN	Bel300	4	Oxy60	4	2203.03	1866.36	407	1.18	0.2385	0.05	-1465.89	5871.95
TRTPN*ATPTN	Bel300	4	Plac	0	-2414.16	1865.61	407	-1.29	0.1964	0.05	-6081.59	1253.27
TRTPN*ATPTN	Bel300	4	Plac	0.5	-3994.55	1865.61	407	-2.14	0.0329	0.05	-7661.98	-327.12
TRTPN*ATPTN	Bel300	4	Plac	1	-4883.81	1865.61	407	-2.62	0.0092	0.05	-8551.24	-1216.38

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	4	Plac	2	-1078.35	1865.61	407	-0.58	0.5636	0.05	-4745.78	2589.08
TRTPN*ATPTN	Bel300	4	Plac	3	-880.33	1865.61	407	-0.47	0.6373	0.05	-4547.75	2787.10
TRTPN*ATPTN	Bel300	4	Plac	4	-2273.17	1865.61	407	-1.22	0.2238	0.05	-5940.60	1394.26
TRTPN*ATPTN	Bel600	0	Bel600	0.5	-900.50	1930.37	407	-0.47	0.6411	0.05	-4695.24	2894.24
TRTPN*ATPTN	Bel600	0	Bel600	1	467.56	1899.21	407	0.25	0.8057	0.05	-3265.93	4201.04
TRTPN*ATPTN	Bel600	0	Bel600	2	2037.23	1899.21	407	1.07	0.2841	0.05	-1696.26	5770.71
TRTPN*ATPTN	Bel600	0	Bel600	3	2626.45	1899.21	407	1.38	0.1674	0.05	-1107.04	6359.93
TRTPN*ATPTN	Bel600	0	Bel600	4	2610.19	1899.21	407	1.37	0.1701	0.05	-1123.30	6343.67
TRTPN*ATPTN	Bel600	0	Bel900	0	-1576.80	1933.90	407	-0.82	0.4154	0.05	-5378.48	2224.88
TRTPN*ATPTN	Bel600	0	Bel900	0.5	-3022.23	1899.91	407	-1.59	0.1124	0.05	-6757.09	712.64
TRTPN*ATPTN	Bel600	0	Bel900	1	-202.75	1899.91	407	-0.11	0.9151	0.05	-3937.62	3532.11
TRTPN*ATPTN	Bel600	0	Bel900	2	1555.00	1899.91	407	0.82	0.4136	0.05	-2179.86	5289.86
TRTPN*ATPTN	Bel600	0	Bel900	3	2235.27	1899.91	407	1.18	0.2401	0.05	-1499.60	5970.13
TRTPN*ATPTN	Bel600	0	Bel900	4	3283.75	1899.91	407	1.73	0.0847	0.05	-451.11	7018.62
TRTPN*ATPTN	Bel600	0	Oxy30	0	-370.24	1971.65	407	-0.19	0.8511	0.05	-4246.13	3505.65
TRTPN*ATPTN	Bel600	0	Oxy30	0.5	1901.91	1971.65	407	0.96	0.3353	0.05	-1973.99	5777.80
TRTPN*ATPTN	Bel600	0	Oxy30	1	3754.91	1933.14	407	1.94	0.0528	0.05	-45.2754	7555.10
TRTPN*ATPTN	Bel600	0	Oxy30	2	2899.17	1899.96	407	1.53	0.1278	0.05	-835.79	6634.13
TRTPN*ATPTN	Bel600	0	Oxy30	3	1304.33	1899.96	407	0.69	0.4928	0.05	-2430.63	5039.29
TRTPN*ATPTN	Bel600	0	Oxy30	4	1083.58	1899.96	407	0.57	0.5688	0.05	-2651.38	4818.53
TRTPN*ATPTN	Bel600	0	Oxy60	0	718.45	1973.27	407	0.36	0.7160	0.05	-3160.62	4597.53
TRTPN*ATPTN	Bel600	0	Oxy60	0.5	3088.30	1973.27	407	1.57	0.1183	0.05	-790.78	6967.37
TRTPN*ATPTN	Bel600	0	Oxy60	1	5384.16	1935.61	407	2.78	0.0057	0.05	1579.12	9189.20
TRTPN*ATPTN	Bel600	0	Oxy60	2	6606.39	1900.72	407	3.48	0.0006	0.05	2869.93	10343
TRTPN*ATPTN	Bel600	0	Oxy60	3	6056.92	1900.72	407	3.19	0.0016	0.05	2320.46	9793.38

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel600	0	Oxy60	4	5936.78	1900.72	407	3.12	0.0019	0.05	2200.32	9673.24
TRTPN*ATPTN	Bel600	0	Plac	0	1319.59	1899.90	407	0.69	0.4877	0.05	-2415.26	5054.44
TRTPN*ATPTN	Bel600	0	Plac	0.5	-260.80	1899.90	407	-0.14	0.8909	0.05	-3995.64	3474.05
TRTPN*ATPTN	Bel600	0	Plac	1	-1150.06	1899.90	407	-0.61	0.5453	0.05	-4884.90	2584.79
TRTPN*ATPTN	Bel600	0	Plac	2	2655.41	1899.90	407	1.40	0.1630	0.05	-1079.44	6390.25
TRTPN*ATPTN	Bel600	0	Plac	3	2853.43	1899.90	407	1.50	0.1339	0.05	-881.42	6588.27
TRTPN*ATPTN	Bel600	0	Plac	4	1460.58	1899.90	407	0.77	0.4425	0.05	-2274.26	5195.43
TRTPN*ATPTN	Bel600	0.5	Bel600	1	1368.05	1899.21	407	0.72	0.4717	0.05	-2365.43	5101.54
TRTPN*ATPTN	Bel600	0.5	Bel600	2	2937.73	1899.21	407	1.55	0.1227	0.05	-795.76	6671.21
TRTPN*ATPTN	Bel600	0.5	Bel600	3	3526.94	1899.21	407	1.86	0.0640	0.05	-206.54	7260.43
TRTPN*ATPTN	Bel600	0.5	Bel600	4	3510.68	1899.21	407	1.85	0.0653	0.05	-222.80	7244.17
TRTPN*ATPTN	Bel600	0.5	Bel900	0	-676.30	1933.90	407	-0.35	0.7267	0.05	-4477.98	3125.38
TRTPN*ATPTN	Bel600	0.5	Bel900	0.5	-2121.73	1899.91	407	-1.12	0.2648	0.05	-5856.59	1613.13
TRTPN*ATPTN	Bel600	0.5	Bel900	1	697.74	1899.91	407	0.37	0.7136	0.05	-3037.12	4432.61
TRTPN*ATPTN	Bel600	0.5	Bel900	2	2455.50	1899.91	407	1.29	0.1969	0.05	-1279.36	6190.36
TRTPN*ATPTN	Bel600	0.5	Bel900	3	3135.76	1899.91	407	1.65	0.0996	0.05	-599.10	6870.63
TRTPN*ATPTN	Bel600	0.5	Bel900	4	4184.25	1899.91	407	2.20	0.0282	0.05	449.39	7919.11
TRTPN*ATPTN	Bel600	0.5	Oxy30	0	530.25	1971.65	407	0.27	0.7881	0.05	-3345.64	4406.15
TRTPN*ATPTN	Bel600	0.5	Oxy30	0.5	2802.40	1971.65	407	1.42	0.1560	0.05	-1073.49	6678.29
TRTPN*ATPTN	Bel600	0.5	Oxy30	1	4655.41	1933.14	407	2.41	0.0165	0.05	855.22	8455.60
TRTPN*ATPTN	Bel600	0.5	Oxy30	2	3799.67	1899.96	407	2.00	0.0462	0.05	64.7109	7534.62
TRTPN*ATPTN	Bel600	0.5	Oxy30	3	2204.83	1899.96	407	1.16	0.2465	0.05	-1530.13	5939.78
TRTPN*ATPTN	Bel600	0.5	Oxy30	4	1984.08	1899.96	407	1.04	0.2970	0.05	-1750.88	5719.03
TRTPN*ATPTN	Bel600	0.5	Oxy60	0	1618.95	1973.27	407	0.82	0.4124	0.05	-2260.13	5498.03
TRTPN*ATPTN	Bel600	0.5	Oxy60	0.5	3988.79	1973.27	407	2.02	0.0439	0.05	109.72	7867.87

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel600	0.5	Oxy60	1	6284.66	1935.61	407	3.25	0.0013	0.05	2479.62	10090
TRTPN*ATPTN	Bel600	0.5	Oxy60	2	7506.89	1900.72	407	3.95	<.0001	0.05	3770.43	11243
TRTPN*ATPTN	Bel600	0.5	Oxy60	3	6957.41	1900.72	407	3.66	0.0003	0.05	3220.95	10694
TRTPN*ATPTN	Bel600	0.5	Oxy60	4	6837.28	1900.72	407	3.60	0.0004	0.05	3100.82	10574
TRTPN*ATPTN	Bel600	0.5	Plac	0	2220.09	1899.90	407	1.17	0.2433	0.05	-1514.76	5954.93
TRTPN*ATPTN	Bel600	0.5	Plac	0.5	639.70	1899.90	407	0.34	0.7365	0.05	-3095.15	4374.55
TRTPN*ATPTN	Bel600	0.5	Plac	1	-249.56	1899.90	407	-0.13	0.8956	0.05	-3984.41	3485.29
TRTPN*ATPTN	Bel600	0.5	Plac	2	3555.90	1899.90	407	1.87	0.0620	0.05	-178.94	7290.75
TRTPN*ATPTN	Bel600	0.5	Plac	3	3753.92	1899.90	407	1.98	0.0488	0.05	19.0786	7488.77
TRTPN*ATPTN	Bel600	0.5	Plac	4	2361.08	1899.90	407	1.24	0.2147	0.05	-1373.77	6095.93
TRTPN*ATPTN	Bel600	1	Bel600	2	1569.67	1864.91	407	0.84	0.4005	0.05	-2096.39	5235.74
TRTPN*ATPTN	Bel600	1	Bel600	3	2158.89	1864.91	407	1.16	0.2477	0.05	-1507.18	5824.96
TRTPN*ATPTN	Bel600	1	Bel600	4	2142.63	1864.91	407	1.15	0.2513	0.05	-1523.44	5808.70
TRTPN*ATPTN	Bel600	1	Bel900	0	-2044.36	1900.65	407	-1.08	0.2827	0.05	-5780.66	1691.95
TRTPN*ATPTN	Bel600	1	Bel900	0.5	-3489.78	1866.36	407	-1.87	0.0622	0.05	-7158.69	179.13
TRTPN*ATPTN	Bel600	1	Bel900	1	-670.31	1866.36	407	-0.36	0.7197	0.05	-4339.22	2998.60
TRTPN*ATPTN	Bel600	1	Bel900	2	1087.45	1866.36	407	0.58	0.5604	0.05	-2581.47	4756.36
TRTPN*ATPTN	Bel600	1	Bel900	3	1767.71	1866.36	407	0.95	0.3441	0.05	-1901.20	5436.62
TRTPN*ATPTN	Bel600	1	Bel900	4	2816.20	1866.36	407	1.51	0.1321	0.05	-852.71	6485.11
TRTPN*ATPTN	Bel600	1	Oxy30	0	-837.80	1939.83	407	-0.43	0.6660	0.05	-4651.14	2975.54
TRTPN*ATPTN	Bel600	1	Oxy30	0.5	1434.35	1939.83	407	0.74	0.4601	0.05	-2378.99	5247.69
TRTPN*ATPTN	Bel600	1	Oxy30	1	3287.36	1900.00	407	1.73	0.0844	0.05	-447.69	7022.40
TRTPN*ATPTN	Bel600	1	Oxy30	2	2431.61	1865.62	407	1.30	0.1932	0.05	-1235.83	6099.06
TRTPN*ATPTN	Bel600	1	Oxy30	3	836.78	1865.62	407	0.45	0.6540	0.05	-2830.67	4504.22
TRTPN*ATPTN	Bel600	1	Oxy30	4	616.02	1865.62	407	0.33	0.7414	0.05	-3051.42	4283.47

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel600	1	Oxy60	0	250.90	1940.37	407	0.13	0.8972	0.05	-3563.50	4065.30
TRTPN*ATPTN	Bel600	1	Oxy60	0.5	2620.74	1940.37	407	1.35	0.1776	0.05	-1193.66	6435.14
TRTPN*ATPTN	Bel600	1	Oxy60	1	4916.60	1901.48	407	2.59	0.0101	0.05	1178.66	8654.55
TRTPN*ATPTN	Bel600	1	Oxy60	2	6138.83	1866.33	407	3.29	0.0011	0.05	2469.98	9807.69
TRTPN*ATPTN	Bel600	1	Oxy60	3	5589.36	1866.33	407	2.99	0.0029	0.05	1920.50	9258.22
TRTPN*ATPTN	Bel600	1	Oxy60	4	5469.23	1866.33	407	2.93	0.0036	0.05	1800.37	9138.08
TRTPN*ATPTN	Bel600	1	Plac	0	852.03	1866.36	407	0.46	0.6483	0.05	-2816.87	4520.94
TRTPN*ATPTN	Bel600	1	Plac	0.5	-728.35	1866.36	407	-0.39	0.6966	0.05	-4397.26	2940.55
TRTPN*ATPTN	Bel600	1	Plac	1	-1617.61	1866.36	407	-0.87	0.3866	0.05	-5286.52	2051.29
TRTPN*ATPTN	Bel600	1	Plac	2	2187.85	1866.36	407	1.17	0.2418	0.05	-1481.05	5856.75
TRTPN*ATPTN	Bel600	1	Plac	3	2385.87	1866.36	407	1.28	0.2019	0.05	-1283.03	6054.78
TRTPN*ATPTN	Bel600	1	Plac	4	993.03	1866.36	407	0.53	0.5950	0.05	-2675.88	4661.93
TRTPN*ATPTN	Bel600	2	Bel600	3	589.22	1864.91	407	0.32	0.7522	0.05	-3076.85	4255.28
TRTPN*ATPTN	Bel600	2	Bel600	4	572.96	1864.91	407	0.31	0.7588	0.05	-3093.11	4239.02
TRTPN*ATPTN	Bel600	2	Bel900	0	-3614.03	1900.65	407	-1.90	0.0579	0.05	-7350.33	122.28
TRTPN*ATPTN	Bel600	2	Bel900	0.5	-5059.45	1866.36	407	-2.71	0.0070	0.05	-8728.37	-1390.54
TRTPN*ATPTN	Bel600	2	Bel900	1	-2239.98	1866.36	407	-1.20	0.2308	0.05	-5908.89	1428.93
TRTPN*ATPTN	Bel600	2	Bel900	2	-482.23	1866.36	407	-0.26	0.7962	0.05	-4151.14	3186.69
TRTPN*ATPTN	Bel600	2	Bel900	3	198.04	1866.36	407	0.11	0.9155	0.05	-3470.87	3866.95
TRTPN*ATPTN	Bel600	2	Bel900	4	1246.53	1866.36	407	0.67	0.5046	0.05	-2422.39	4915.44
TRTPN*ATPTN	Bel600	2	Oxy30	0	-2407.47	1939.83	407	-1.24	0.2153	0.05	-6220.81	1405.87
TRTPN*ATPTN	Bel600	2	Oxy30	0.5	-135.32	1939.83	407	-0.07	0.9444	0.05	-3948.66	3678.02
TRTPN*ATPTN	Bel600	2	Oxy30	1	1717.69	1900.00	407	0.90	0.3665	0.05	-2017.36	5452.73
TRTPN*ATPTN	Bel600	2	Oxy30	2	861.94	1865.62	407	0.46	0.6443	0.05	-2805.51	4529.39
TRTPN*ATPTN	Bel600	2	Oxy30	3	-732.90	1865.62	407	-0.39	0.6946	0.05	-4400.34	2934.55

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel600	2	Oxy30	4	-953.65	1865.62	407	-0.51	0.6095	0.05	-4621.10	2713.80
TRTPN*ATPTN	Bel600	2	Oxy60	0	-1318.78	1940.37	407	-0.68	0.4971	0.05	-5133.18	2495.63
TRTPN*ATPTN	Bel600	2	Oxy60	0.5	1051.07	1940.37	407	0.54	0.5883	0.05	-2763.33	4865.47
TRTPN*ATPTN	Bel600	2	Oxy60	1	3346.93	1901.48	407	1.76	0.0791	0.05	-391.02	7084.88
TRTPN*ATPTN	Bel600	2	Oxy60	2	4569.16	1866.33	407	2.45	0.0148	0.05	900.31	8238.02
TRTPN*ATPTN	Bel600	2	Oxy60	3	4019.69	1866.33	407	2.15	0.0318	0.05	350.83	7688.54
TRTPN*ATPTN	Bel600	2	Oxy60	4	3899.55	1866.33	407	2.09	0.0373	0.05	230.70	7568.41
TRTPN*ATPTN	Bel600	2	Plac	0	-717.64	1866.36	407	-0.38	0.7008	0.05	-4386.54	2951.27
TRTPN*ATPTN	Bel600	2	Plac	0.5	-2298.02	1866.36	407	-1.23	0.2189	0.05	-5966.93	1370.88
TRTPN*ATPTN	Bel600	2	Plac	1	-3187.28	1866.36	407	-1.71	0.0884	0.05	-6856.19	481.62
TRTPN*ATPTN	Bel600	2	Plac	2	618.18	1866.36	407	0.33	0.7406	0.05	-3050.73	4287.08
TRTPN*ATPTN	Bel600	2	Plac	3	816.20	1866.36	407	0.44	0.6621	0.05	-2852.71	4485.10
TRTPN*ATPTN	Bel600	2	Plac	4	-576.64	1866.36	407	-0.31	0.7575	0.05	-4245.55	3092.26
TRTPN*ATPTN	Bel600	3	Bel600	4	-16.2605	1864.91	407	-0.01	0.9930	0.05	-3682.33	3649.81
TRTPN*ATPTN	Bel600	3	Bel900	0	-4203.25	1900.65	407	-2.21	0.0276	0.05	-7939.55	-466.94
TRTPN*ATPTN	Bel600	3	Bel900	0.5	-5648.67	1866.36	407	-3.03	0.0026	0.05	-9317.58	-1979.76
TRTPN*ATPTN	Bel600	3	Bel900	1	-2829.20	1866.36	407	-1.52	0.1303	0.05	-6498.11	839.71
TRTPN*ATPTN	Bel600	3	Bel900	2	-1071.44	1866.36	407	-0.57	0.5662	0.05	-4740.36	2597.47
TRTPN*ATPTN	Bel600	3	Bel900	3	-391.18	1866.36	407	-0.21	0.8341	0.05	-4060.09	3277.73
TRTPN*ATPTN	Bel600	3	Bel900	4	657.31	1866.36	407	0.35	0.7249	0.05	-3011.60	4326.22
TRTPN*ATPTN	Bel600	3	Oxy30	0	-2996.69	1939.83	407	-1.54	0.1232	0.05	-6810.03	816.65
TRTPN*ATPTN	Bel600	3	Oxy30	0.5	-724.54	1939.83	407	-0.37	0.7090	0.05	-4537.88	3088.80
TRTPN*ATPTN	Bel600	3	Oxy30	1	1128.47	1900.00	407	0.59	0.5529	0.05	-2606.58	4863.51
TRTPN*ATPTN	Bel600	3	Oxy30	2	272.72	1865.62	407	0.15	0.8838	0.05	-3394.72	3940.17
TRTPN*ATPTN	Bel600	3	Oxy30	3	-1322.11	1865.62	407	-0.71	0.4789	0.05	-4989.56	2345.33

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel600	3	Oxy30	4	-1542.87	1865.62	407	-0.83	0.4087	0.05	-5210.31	2124.58
TRTPN*ATPTN	Bel600	3	Oxy60	0	-1907.99	1940.37	407	-0.98	0.3260	0.05	-5722.39	1906.41
TRTPN*ATPTN	Bel600	3	Oxy60	0.5	461.85	1940.37	407	0.24	0.8120	0.05	-3352.55	4276.25
TRTPN*ATPTN	Bel600	3	Oxy60	1	2757.71	1901.48	407	1.45	0.1477	0.05	-980.23	6495.66
TRTPN*ATPTN	Bel600	3	Oxy60	2	3979.94	1866.33	407	2.13	0.0336	0.05	311.09	7648.80
TRTPN*ATPTN	Bel600	3	Oxy60	3	3430.47	1866.33	407	1.84	0.0668	0.05	-238.39	7099.33
TRTPN*ATPTN	Bel600	3	Oxy60	4	3310.34	1866.33	407	1.77	0.0769	0.05	-358.52	6979.19
TRTPN*ATPTN	Bel600	3	Plac	0	-1306.86	1866.36	407	-0.70	0.4842	0.05	-4975.76	2362.05
TRTPN*ATPTN	Bel600	3	Plac	0.5	-2887.24	1866.36	407	-1.55	0.1226	0.05	-6556.15	781.66
TRTPN*ATPTN	Bel600	3	Plac	1	-3776.50	1866.36	407	-2.02	0.0437	0.05	-7445.41	-107.60
TRTPN*ATPTN	Bel600	3	Plac	2	28.9600	1866.36	407	0.02	0.9876	0.05	-3639.94	3697.86
TRTPN*ATPTN	Bel600	3	Plac	3	226.98	1866.36	407	0.12	0.9033	0.05	-3441.92	3895.89
TRTPN*ATPTN	Bel600	3	Plac	4	-1165.86	1866.36	407	-0.62	0.5325	0.05	-4834.77	2503.04
TRTPN*ATPTN	Bel600	4	Bel900	0	-4186.98	1900.65	407	-2.20	0.0282	0.05	-7923.29	-450.68
TRTPN*ATPTN	Bel600	4	Bel900	0.5	-5632.41	1866.36	407	-3.02	0.0027	0.05	-9301.32	-1963.50
TRTPN*ATPTN	Bel600	4	Bel900	1	-2812.94	1866.36	407	-1.51	0.1325	0.05	-6481.85	855.97
TRTPN*ATPTN	Bel600	4	Bel900	2	-1055.18	1866.36	407	-0.57	0.5721	0.05	-4724.10	2613.73
TRTPN*ATPTN	Bel600	4	Bel900	3	-374.92	1866.36	407	-0.20	0.8409	0.05	-4043.83	3293.99
TRTPN*ATPTN	Bel600	4	Bel900	4	673.57	1866.36	407	0.36	0.7184	0.05	-2995.34	4342.48
TRTPN*ATPTN	Bel600	4	Oxy30	0	-2980.43	1939.83	407	-1.54	0.1252	0.05	-6793.77	832.91
TRTPN*ATPTN	Bel600	4	Oxy30	0.5	-708.28	1939.83	407	-0.37	0.7152	0.05	-4521.62	3105.06
TRTPN*ATPTN	Bel600	4	Oxy30	1	1144.73	1900.00	407	0.60	0.5472	0.05	-2590.32	4879.77
TRTPN*ATPTN	Bel600	4	Oxy30	2	288.98	1865.62	407	0.15	0.8770	0.05	-3378.46	3956.43
TRTPN*ATPTN	Bel600	4	Oxy30	3	-1305.85	1865.62	407	-0.70	0.4844	0.05	-4973.30	2361.59
TRTPN*ATPTN	Bel600	4	Oxy30	4	-1526.61	1865.62	407	-0.82	0.4137	0.05	-5194.05	2140.84

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel600	4	Oxy60	0	-1891.73	1940.37	407	-0.97	0.3302	0.05	-5706.13	1922.67
TRTPN*ATPTN	Bel600	4	Oxy60	0.5	478.11	1940.37	407	0.25	0.8055	0.05	-3336.29	4292.51
TRTPN*ATPTN	Bel600	4	Oxy60	1	2773.97	1901.48	407	1.46	0.1454	0.05	-963.97	6511.92
TRTPN*ATPTN	Bel600	4	Oxy60	2	3996.20	1866.33	407	2.14	0.0329	0.05	327.35	7665.06
TRTPN*ATPTN	Bel600	4	Oxy60	3	3446.73	1866.33	407	1.85	0.0655	0.05	-222.12	7115.59
TRTPN*ATPTN	Bel600	4	Oxy60	4	3326.60	1866.33	407	1.78	0.0754	0.05	-342.26	6995.45
TRTPN*ATPTN	Bel600	4	Plac	0	-1290.60	1866.36	407	-0.69	0.4896	0.05	-4959.50	2378.31
TRTPN*ATPTN	Bel600	4	Plac	0.5	-2870.98	1866.36	407	-1.54	0.1248	0.05	-6539.89	797.92
TRTPN*ATPTN	Bel600	4	Plac	1	-3760.24	1866.36	407	-2.01	0.0446	0.05	-7429.15	-91.3370
TRTPN*ATPTN	Bel600	4	Plac	2	45.2205	1866.36	407	0.02	0.9807	0.05	-3623.68	3714.13
TRTPN*ATPTN	Bel600	4	Plac	3	243.24	1866.36	407	0.13	0.8964	0.05	-3425.66	3912.15
TRTPN*ATPTN	Bel600	4	Plac	4	-1149.60	1866.36	407	-0.62	0.5383	0.05	-4818.51	2519.30
TRTPN*ATPTN	Bel900	0	Bel900	0.5	-1445.43	1899.15	407	-0.76	0.4470	0.05	-5178.80	2287.94
TRTPN*ATPTN	Bel900	0	Bel900	1	1374.05	1899.15	407	0.72	0.4698	0.05	-2359.32	5107.42
TRTPN*ATPTN	Bel900	0	Bel900	2	3131.80	1899.15	407	1.65	0.0999	0.05	-601.57	6865.17
TRTPN*ATPTN	Bel900	0	Bel900	3	3812.07	1899.15	407	2.01	0.0454	0.05	78.6944	7545.44
TRTPN*ATPTN	Bel900	0	Bel900	4	4860.55	1899.15	407	2.56	0.0108	0.05	1127.18	8593.93
TRTPN*ATPTN	Bel900	0	Oxy30	0	1206.56	1972.55	407	0.61	0.5411	0.05	-2671.09	5084.21
TRTPN*ATPTN	Bel900	0	Oxy30	0.5	3478.71	1972.55	407	1.76	0.0786	0.05	-398.94	7356.35
TRTPN*ATPTN	Bel900	0	Oxy30	1	5331.71	1933.93	407	2.76	0.0061	0.05	1529.98	9133.44
TRTPN*ATPTN	Bel900	0	Oxy30	2	4475.97	1900.64	407	2.35	0.0190	0.05	739.68	8212.26
TRTPN*ATPTN	Bel900	0	Oxy30	3	2881.13	1900.64	407	1.52	0.1303	0.05	-855.16	6617.42
TRTPN*ATPTN	Bel900	0	Oxy30	4	2660.38	1900.64	407	1.40	0.1624	0.05	-1075.92	6396.67
TRTPN*ATPTN	Bel900	0	Oxy60	0	2295.25	1970.63	407	1.16	0.2448	0.05	-1578.63	6169.13
TRTPN*ATPTN	Bel900	0	Oxy60	0.5	4665.10	1970.63	407	2.37	0.0184	0.05	791.22	8538.98

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel900	0	Oxy60	1	6960.96	1933.11	407	3.60	0.0004	0.05	3160.84	10761
TRTPN*ATPTN	Bel900	0	Oxy60	2	8183.19	1899.14	407	4.31	<.0001	0.05	4449.84	11917
TRTPN*ATPTN	Bel900	0	Oxy60	3	7633.72	1899.14	407	4.02	<.0001	0.05	3900.36	11367
TRTPN*ATPTN	Bel900	0	Oxy60	4	7513.58	1899.14	407	3.96	<.0001	0.05	3780.23	11247
TRTPN*ATPTN	Bel900	0	Plac	0	2896.39	1899.87	407	1.52	0.1282	0.05	-838.39	6631.17
TRTPN*ATPTN	Bel900	0	Plac	0.5	1316.00	1899.87	407	0.69	0.4889	0.05	-2418.78	5050.78
TRTPN*ATPTN	Bel900	0	Plac	1	426.74	1899.87	407	0.22	0.8224	0.05	-3308.04	4161.53
TRTPN*ATPTN	Bel900	0	Plac	2	4232.21	1899.87	407	2.23	0.0265	0.05	497.42	7966.99
TRTPN*ATPTN	Bel900	0	Plac	3	4430.23	1899.87	407	2.33	0.0202	0.05	695.44	8165.01
TRTPN*ATPTN	Bel900	0	Plac	4	3037.38	1899.87	407	1.60	0.1107	0.05	-697.40	6772.17
TRTPN*ATPTN	Bel900	0.5	Bel900	1	2819.47	1864.91	407	1.51	0.1313	0.05	-846.59	6485.54
TRTPN*ATPTN	Bel900	0.5	Bel900	2	4577.23	1864.91	407	2.45	0.0145	0.05	911.16	8243.29
TRTPN*ATPTN	Bel900	0.5	Bel900	3	5257.49	1864.91	407	2.82	0.0051	0.05	1591.43	8923.56
TRTPN*ATPTN	Bel900	0.5	Bel900	4	6305.98	1864.91	407	3.38	0.0008	0.05	2639.92	9972.05
TRTPN*ATPTN	Bel900	0.5	Oxy30	0	2651.98	1938.86	407	1.37	0.1721	0.05	-1159.45	6463.42
TRTPN*ATPTN	Bel900	0.5	Oxy30	0.5	4924.13	1938.86	407	2.54	0.0115	0.05	1112.69	8735.57
TRTPN*ATPTN	Bel900	0.5	Oxy30	1	6777.14	1899.92	407	3.57	0.0004	0.05	3042.26	10512
TRTPN*ATPTN	Bel900	0.5	Oxy30	2	5921.40	1866.35	407	3.17	0.0016	0.05	2252.51	9590.28
TRTPN*ATPTN	Bel900	0.5	Oxy30	3	4326.56	1866.35	407	2.32	0.0209	0.05	657.67	7995.44
TRTPN*ATPTN	Bel900	0.5	Oxy30	4	4105.80	1866.35	407	2.20	0.0284	0.05	436.92	7774.69
TRTPN*ATPTN	Bel900	0.5	Oxy60	0	3740.68	1937.93	407	1.93	0.0543	0.05	-68.9214	7550.28
TRTPN*ATPTN	Bel900	0.5	Oxy60	0.5	6110.52	1937.93	407	3.15	0.0017	0.05	2300.92	9920.12
TRTPN*ATPTN	Bel900	0.5	Oxy60	1	8406.39	1900.81	407	4.42	<.0001	0.05	4669.76	12143
TRTPN*ATPTN	Bel900	0.5	Oxy60	2	9628.62	1865.66	407	5.16	<.0001	0.05	5961.08	13296
TRTPN*ATPTN	Bel900	0.5	Oxy60	3	9079.14	1865.66	407	4.87	<.0001	0.05	5411.61	12747

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel900	0.5	Oxy60	4	8959.01	1865.66	407	4.80	<.0001	0.05	5291.47	12627
TRTPN*ATPTN	Bel900	0.5	Plac	0	4341.82	1866.33	407	2.33	0.0205	0.05	672.97	8010.66
TRTPN*ATPTN	Bel900	0.5	Plac	0.5	2761.43	1866.33	407	1.48	0.1398	0.05	-907.42	6430.27
TRTPN*ATPTN	Bel900	0.5	Plac	1	1872.17	1866.33	407	1.00	0.3164	0.05	-1796.68	5541.02
TRTPN*ATPTN	Bel900	0.5	Plac	2	5677.63	1866.33	407	3.04	0.0025	0.05	2008.79	9346.48
TRTPN*ATPTN	Bel900	0.5	Plac	3	5875.65	1866.33	407	3.15	0.0018	0.05	2206.81	9544.50
TRTPN*ATPTN	Bel900	0.5	Plac	4	4482.81	1866.33	407	2.40	0.0168	0.05	813.96	8151.66
TRTPN*ATPTN	Bel900	1	Bel900	2	1757.75	1864.91	407	0.94	0.3465	0.05	-1908.31	5423.82
TRTPN*ATPTN	Bel900	1	Bel900	3	2438.02	1864.91	407	1.31	0.1918	0.05	-1228.05	6104.08
TRTPN*ATPTN	Bel900	1	Bel900	4	3486.51	1864.91	407	1.87	0.0623	0.05	-179.56	7152.57
TRTPN*ATPTN	Bel900	1	Oxy30	0	-167.49	1938.86	407	-0.09	0.9312	0.05	-3978.93	3643.95
TRTPN*ATPTN	Bel900	1	Oxy30	0.5	2104.66	1938.86	407	1.09	0.2783	0.05	-1706.78	5916.10
TRTPN*ATPTN	Bel900	1	Oxy30	1	3957.67	1899.92	407	2.08	0.0379	0.05	222.79	7692.54
TRTPN*ATPTN	Bel900	1	Oxy30	2	3101.92	1866.35	407	1.66	0.0973	0.05	-566.96	6770.81
TRTPN*ATPTN	Bel900	1	Oxy30	3	1507.08	1866.35	407	0.81	0.4198	0.05	-2161.80	5175.97
TRTPN*ATPTN	Bel900	1	Oxy30	4	1286.33	1866.35	407	0.69	0.4911	0.05	-2382.56	4955.22
TRTPN*ATPTN	Bel900	1	Oxy60	0	921.20	1937.93	407	0.48	0.6348	0.05	-2888.39	4730.80
TRTPN*ATPTN	Bel900	1	Oxy60	0.5	3291.05	1937.93	407	1.70	0.0902	0.05	-518.55	7100.65
TRTPN*ATPTN	Bel900	1	Oxy60	1	5586.91	1900.81	407	2.94	0.0035	0.05	1850.29	9323.53
TRTPN*ATPTN	Bel900	1	Oxy60	2	6809.14	1865.66	407	3.65	0.0003	0.05	3141.61	10477
TRTPN*ATPTN	Bel900	1	Oxy60	3	6259.67	1865.66	407	3.36	0.0009	0.05	2592.14	9927.20
TRTPN*ATPTN	Bel900	1	Oxy60	4	6139.53	1865.66	407	3.29	0.0011	0.05	2472.00	9807.07
TRTPN*ATPTN	Bel900	1	Plac	0	1522.34	1866.33	407	0.82	0.4152	0.05	-2146.50	5191.19
TRTPN*ATPTN	Bel900	1	Plac	0.5	-58.0443	1866.33	407	-0.03	0.9752	0.05	-3726.89	3610.80
TRTPN*ATPTN	Bel900	1	Plac	1	-947.30	1866.33	407	-0.51	0.6120	0.05	-4616.15	2721.54

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel900	1	Plac	2	2858.16	1866.33	407	1.53	0.1264	0.05	-810.69	6527.00
TRTPN*ATPTN	Bel900	1	Plac	3	3056.18	1866.33	407	1.64	0.1023	0.05	-612.67	6725.03
TRTPN*ATPTN	Bel900	1	Plac	4	1663.34	1866.33	407	0.89	0.3733	0.05	-2005.51	5332.18
TRTPN*ATPTN	Bel900	2	Bel900	3	680.26	1864.91	407	0.36	0.7155	0.05	-2985.80	4346.33
TRTPN*ATPTN	Bel900	2	Bel900	4	1728.75	1864.91	407	0.93	0.3545	0.05	-1937.31	5394.82
TRTPN*ATPTN	Bel900	2	Oxy30	0	-1925.24	1938.86	407	-0.99	0.3213	0.05	-5736.68	1886.19
TRTPN*ATPTN	Bel900	2	Oxy30	0.5	346.90	1938.86	407	0.18	0.8581	0.05	-3464.53	4158.34
TRTPN*ATPTN	Bel900	2	Oxy30	1	2199.91	1899.92	407	1.16	0.2476	0.05	-1534.96	5934.79
TRTPN*ATPTN	Bel900	2	Oxy30	2	1344.17	1866.35	407	0.72	0.4718	0.05	-2324.72	5013.06
TRTPN*ATPTN	Bel900	2	Oxy30	3	-250.67	1866.35	407	-0.13	0.8932	0.05	-3919.56	3418.22
TRTPN*ATPTN	Bel900	2	Oxy30	4	-471.42	1866.35	407	-0.25	0.8007	0.05	-4140.31	3197.46
TRTPN*ATPTN	Bel900	2	Oxy60	0	-836.55	1937.93	407	-0.43	0.6662	0.05	-4646.15	2973.05
TRTPN*ATPTN	Bel900	2	Oxy60	0.5	1533.29	1937.93	407	0.79	0.4293	0.05	-2276.31	5342.89
TRTPN*ATPTN	Bel900	2	Oxy60	1	3829.16	1900.81	407	2.01	0.0446	0.05	92.5345	7565.78
TRTPN*ATPTN	Bel900	2	Oxy60	2	5051.39	1865.66	407	2.71	0.0071	0.05	1383.85	8718.92
TRTPN*ATPTN	Bel900	2	Oxy60	3	4501.91	1865.66	407	2.41	0.0163	0.05	834.38	8169.45
TRTPN*ATPTN	Bel900	2	Oxy60	4	4381.78	1865.66	407	2.35	0.0193	0.05	714.25	8049.31
TRTPN*ATPTN	Bel900	2	Plac	0	-235.41	1866.33	407	-0.13	0.8997	0.05	-3904.26	3433.43
TRTPN*ATPTN	Bel900	2	Plac	0.5	-1815.80	1866.33	407	-0.97	0.3312	0.05	-5484.64	1853.05
TRTPN*ATPTN	Bel900	2	Plac	1	-2705.06	1866.33	407	-1.45	0.1480	0.05	-6373.90	963.79
TRTPN*ATPTN	Bel900	2	Plac	2	1100.40	1866.33	407	0.59	0.5558	0.05	-2568.44	4769.25
TRTPN*ATPTN	Bel900	2	Plac	3	1298.43	1866.33	407	0.70	0.4870	0.05	-2370.42	4967.27
TRTPN*ATPTN	Bel900	2	Plac	4	-94.4181	1866.33	407	-0.05	0.9597	0.05	-3763.26	3574.43
TRTPN*ATPTN	Bel900	3	Bel900	4	1048.49	1864.91	407	0.56	0.5743	0.05	-2617.58	4714.55
TRTPN*ATPTN	Bel900	3	Oxy30	0	-2605.51	1938.86	407	-1.34	0.1798	0.05	-6416.95	1205.93

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel900	3	Oxy30	0.5	-333.36	1938.86	407	-0.17	0.8636	0.05	-4144.80	3478.08
TRTPN*ATPTN	Bel900	3	Oxy30	1	1519.65	1899.92	407	0.80	0.4243	0.05	-2215.23	5254.52
TRTPN*ATPTN	Bel900	3	Oxy30	2	663.90	1866.35	407	0.36	0.7222	0.05	-3004.98	4332.79
TRTPN*ATPTN	Bel900	3	Oxy30	3	-930.93	1866.35	407	-0.50	0.6182	0.05	-4599.82	2737.95
TRTPN*ATPTN	Bel900	3	Oxy30	4	-1151.69	1866.35	407	-0.62	0.5375	0.05	-4820.57	2517.20
TRTPN*ATPTN	Bel900	3	Oxy60	0	-1516.81	1937.93	407	-0.78	0.4343	0.05	-5326.41	2292.79
TRTPN*ATPTN	Bel900	3	Oxy60	0.5	853.03	1937.93	407	0.44	0.6600	0.05	-2956.57	4662.63
TRTPN*ATPTN	Bel900	3	Oxy60	1	3148.89	1900.81	407	1.66	0.0984	0.05	-587.73	6885.52
TRTPN*ATPTN	Bel900	3	Oxy60	2	4371.12	1865.66	407	2.34	0.0196	0.05	703.59	8038.66
TRTPN*ATPTN	Bel900	3	Oxy60	3	3821.65	1865.66	407	2.05	0.0412	0.05	154.12	7489.18
TRTPN*ATPTN	Bel900	3	Oxy60	4	3701.52	1865.66	407	1.98	0.0479	0.05	33.9823	7369.05
TRTPN*ATPTN	Bel900	3	Plac	0	-915.68	1866.33	407	-0.49	0.6240	0.05	-4584.52	2753.17
TRTPN*ATPTN	Bel900	3	Plac	0.5	-2496.06	1866.33	407	-1.34	0.1818	0.05	-6164.91	1172.78
TRTPN*ATPTN	Bel900	3	Plac	1	-3385.32	1866.33	407	-1.81	0.0704	0.05	-7054.17	283.52
TRTPN*ATPTN	Bel900	3	Plac	2	420.14	1866.33	407	0.23	0.8220	0.05	-3248.71	4088.99
TRTPN*ATPTN	Bel900	3	Plac	3	618.16	1866.33	407	0.33	0.7407	0.05	-3050.68	4287.01
TRTPN*ATPTN	Bel900	3	Plac	4	-774.68	1866.33	407	-0.42	0.6783	0.05	-4443.53	2894.16
TRTPN*ATPTN	Bel900	4	Oxy30	0	-3654.00	1938.86	407	-1.88	0.0602	0.05	-7465.44	157.44
TRTPN*ATPTN	Bel900	4	Oxy30	0.5	-1381.85	1938.86	407	-0.71	0.4764	0.05	-5193.29	2429.59
TRTPN*ATPTN	Bel900	4	Oxy30	1	471.16	1899.92	407	0.25	0.8043	0.05	-3263.72	4206.03
TRTPN*ATPTN	Bel900	4	Oxy30	2	-384.59	1866.35	407	-0.21	0.8368	0.05	-4053.47	3284.30
TRTPN*ATPTN	Bel900	4	Oxy30	3	-1979.42	1866.35	407	-1.06	0.2895	0.05	-5648.31	1689.46
TRTPN*ATPTN	Bel900	4	Oxy30	4	-2200.18	1866.35	407	-1.18	0.2391	0.05	-5869.06	1468.71
TRTPN*ATPTN	Bel900	4	Oxy60	0	-2565.30	1937.93	407	-1.32	0.1863	0.05	-6374.90	1244.30
TRTPN*ATPTN	Bel900	4	Oxy60	0.5	-195.46	1937.93	407	-0.10	0.9197	0.05	-4005.06	3614.14

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel900	4	Oxy60	1	2100.40	1900.81	407	1.11	0.2698	0.05	-1636.22	5837.03
TRTPN*ATPTN	Bel900	4	Oxy60	2	3322.64	1865.66	407	1.78	0.0757	0.05	-344.90	6990.17
TRTPN*ATPTN	Bel900	4	Oxy60	3	2773.16	1865.66	407	1.49	0.1379	0.05	-894.37	6440.69
TRTPN*ATPTN	Bel900	4	Oxy60	4	2653.03	1865.66	407	1.42	0.1558	0.05	-1014.51	6320.56
TRTPN*ATPTN	Bel900	4	Plac	0	-1964.16	1866.33	407	-1.05	0.2932	0.05	-5633.01	1704.68
TRTPN*ATPTN	Bel900	4	Plac	0.5	-3544.55	1866.33	407	-1.90	0.0582	0.05	-7213.40	124.29
TRTPN*ATPTN	Bel900	4	Plac	1	-4433.81	1866.33	407	-2.38	0.0180	0.05	-8102.66	-764.97
TRTPN*ATPTN	Bel900	4	Plac	2	-628.35	1866.33	407	-0.34	0.7365	0.05	-4297.19	3040.50
TRTPN*ATPTN	Bel900	4	Plac	3	-430.33	1866.33	407	-0.23	0.8178	0.05	-4099.17	3238.52
TRTPN*ATPTN	Bel900	4	Plac	4	-1823.17	1866.33	407	-0.98	0.3292	0.05	-5492.02	1845.67
TRTPN*ATPTN	Oxy30	0	Oxy30	0.5	2272.15	2003.24	407	1.13	0.2574	0.05	-1665.84	6210.13
TRTPN*ATPTN	Oxy30	0	Oxy30	1	4125.16	1968.65	407	2.10	0.0368	0.05	255.17	7995.14
TRTPN*ATPTN	Oxy30	0	Oxy30	2	3269.41	1939.06	407	1.69	0.0925	0.05	-542.40	7081.23
TRTPN*ATPTN	Oxy30	0	Oxy30	3	1674.57	1939.06	407	0.86	0.3883	0.05	-2137.24	5486.39
TRTPN*ATPTN	Oxy30	0	Oxy30	4	1453.82	1939.06	407	0.75	0.4538	0.05	-2357.99	5265.63
TRTPN*ATPTN	Oxy30	0	Oxy60	0	1088.69	2010.59	407	0.54	0.5885	0.05	-2863.74	5041.13
TRTPN*ATPTN	Oxy30	0	Oxy60	0.5	3458.54	2010.59	407	1.72	0.0862	0.05	-493.90	7410.98
TRTPN*ATPTN	Oxy30	0	Oxy60	1	5754.40	1975.27	407	2.91	0.0038	0.05	1871.40	9637.40
TRTPN*ATPTN	Oxy30	0	Oxy60	2	6976.63	1940.65	407	3.59	0.0004	0.05	3161.68	10792
TRTPN*ATPTN	Oxy30	0	Oxy60	3	6427.16	1940.65	407	3.31	0.0010	0.05	2612.20	10242
TRTPN*ATPTN	Oxy30	0	Oxy60	4	6307.02	1940.65	407	3.25	0.0013	0.05	2492.07	10122
TRTPN*ATPTN	Oxy30	0	Plac	0	1689.83	1938.87	407	0.87	0.3840	0.05	-2121.62	5501.29
TRTPN*ATPTN	Oxy30	0	Plac	0.5	109.45	1938.87	407	0.06	0.9550	0.05	-3702.01	3920.90
TRTPN*ATPTN	Oxy30	0	Plac	1	-779.81	1938.87	407	-0.40	0.6877	0.05	-4591.27	3031.64
TRTPN*ATPTN	Oxy30	0	Plac	2	3025.65	1938.87	407	1.56	0.1194	0.05	-785.81	6837.10

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Oxy30	0	Plac	3	3223.67	1938.87	407	1.66	0.0972	0.05	-587.79	7035.13
TRTPN*ATPTN	Oxy30	0	Plac	4	1830.83	1938.87	407	0.94	0.3456	0.05	-1980.63	5642.28
TRTPN*ATPTN	Oxy30	0.5	Oxy30	1	1853.01	1968.65	407	0.94	0.3471	0.05	-2016.98	5722.99
TRTPN*ATPTN	Oxy30	0.5	Oxy30	2	997.26	1939.06	407	0.51	0.6073	0.05	-2814.55	4809.08
TRTPN*ATPTN	Oxy30	0.5	Oxy30	3	-597.57	1939.06	407	-0.31	0.7581	0.05	-4409.39	3214.24
TRTPN*ATPTN	Oxy30	0.5	Oxy30	4	-818.33	1939.06	407	-0.42	0.6732	0.05	-4630.14	2993.49
TRTPN*ATPTN	Oxy30	0.5	Oxy60	0	-1183.45	2010.59	407	-0.59	0.5564	0.05	-5135.89	2768.98
TRTPN*ATPTN	Oxy30	0.5	Oxy60	0.5	1186.39	2010.59	407	0.59	0.5555	0.05	-2766.05	5138.83
TRTPN*ATPTN	Oxy30	0.5	Oxy60	1	3482.25	1975.27	407	1.76	0.0787	0.05	-400.75	7365.26
TRTPN*ATPTN	Oxy30	0.5	Oxy60	2	4704.48	1940.65	407	2.42	0.0158	0.05	889.53	8519.44
TRTPN*ATPTN	Oxy30	0.5	Oxy60	3	4155.01	1940.65	407	2.14	0.0329	0.05	340.05	7969.97
TRTPN*ATPTN	Oxy30	0.5	Oxy60	4	4034.88	1940.65	407	2.08	0.0382	0.05	219.92	7849.83
TRTPN*ATPTN	Oxy30	0.5	Plac	0	-582.32	1938.87	407	-0.30	0.7641	0.05	-4393.77	3229.14
TRTPN*ATPTN	Oxy30	0.5	Plac	0.5	-2162.70	1938.87	407	-1.12	0.2653	0.05	-5974.16	1648.75
TRTPN*ATPTN	Oxy30	0.5	Plac	1	-3051.96	1938.87	407	-1.57	0.1162	0.05	-6863.42	759.49
TRTPN*ATPTN	Oxy30	0.5	Plac	2	753.50	1938.87	407	0.39	0.6978	0.05	-3057.96	4564.96
TRTPN*ATPTN	Oxy30	0.5	Plac	3	951.52	1938.87	407	0.49	0.6239	0.05	-2859.93	4762.98
TRTPN*ATPTN	Oxy30	0.5	Plac	4	-441.32	1938.87	407	-0.23	0.8201	0.05	-4252.78	3370.13
TRTPN*ATPTN	Oxy30	1	Oxy30	2	-855.74	1899.26	407	-0.45	0.6525	0.05	-4589.34	2877.85
TRTPN*ATPTN	Oxy30	1	Oxy30	3	-2450.58	1899.26	407	-1.29	0.1977	0.05	-6184.17	1283.01
TRTPN*ATPTN	Oxy30	1	Oxy30	4	-2671.33	1899.26	407	-1.41	0.1603	0.05	-6404.93	1062.26
TRTPN*ATPTN	Oxy30	1	Oxy60	0	-3036.46	1972.42	407	-1.54	0.1245	0.05	-6913.87	840.94
TRTPN*ATPTN	Oxy30	1	Oxy60	0.5	-666.62	1972.42	407	-0.34	0.7356	0.05	-4544.02	3210.79
TRTPN*ATPTN	Oxy30	1	Oxy60	1	1629.25	1935.67	407	0.84	0.4005	0.05	-2175.91	5434.40
TRTPN*ATPTN	Oxy30	1	Oxy60	2	2851.48	1900.76	407	1.50	0.1343	0.05	-885.06	6588.02

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Oxy30	1	Oxy60	3	2302.00	1900.76	407	1.21	0.2266	0.05	-1434.54	6038.54
TRTPN*ATPTN	Oxy30	1	Oxy60	4	2181.87	1900.76	407	1.15	0.2517	0.05	-1554.67	5918.41
TRTPN*ATPTN	Oxy30	1	Plac	0	-2435.32	1899.93	407	-1.28	0.2006	0.05	-6170.22	1299.58
TRTPN*ATPTN	Oxy30	1	Plac	0.5	-4015.71	1899.93	407	-2.11	0.0352	0.05	-7750.61	-280.81
TRTPN*ATPTN	Oxy30	1	Plac	1	-4904.97	1899.93	407	-2.58	0.0102	0.05	-8639.87	-1170.07
TRTPN*ATPTN	Oxy30	1	Plac	2	-1099.51	1899.93	407	-0.58	0.5631	0.05	-4834.41	2635.39
TRTPN*ATPTN	Oxy30	1	Plac	3	-901.49	1899.93	407	-0.47	0.6354	0.05	-4636.39	2833.41
TRTPN*ATPTN	Oxy30	1	Plac	4	-2294.33	1899.93	407	-1.21	0.2279	0.05	-6029.23	1440.57
TRTPN*ATPTN	Oxy30	2	Oxy30	3	-1594.84	1864.91	407	-0.86	0.3930	0.05	-5260.90	2071.23
TRTPN*ATPTN	Oxy30	2	Oxy30	4	-1815.59	1864.91	407	-0.97	0.3309	0.05	-5481.66	1850.47
TRTPN*ATPTN	Oxy30	2	Oxy60	0	-2180.72	1939.53	407	-1.12	0.2615	0.05	-5993.46	1632.03
TRTPN*ATPTN	Oxy30	2	Oxy60	0.5	189.13	1939.53	407	0.10	0.9224	0.05	-3623.62	4001.87
TRTPN*ATPTN	Oxy30	2	Oxy60	1	2484.99	1901.48	407	1.31	0.1920	0.05	-1252.95	6222.93
TRTPN*ATPTN	Oxy30	2	Oxy60	2	3707.22	1866.32	407	1.99	0.0477	0.05	38.3874	7376.05
TRTPN*ATPTN	Oxy30	2	Oxy60	3	3157.75	1866.32	407	1.69	0.0914	0.05	-511.09	6826.58
TRTPN*ATPTN	Oxy30	2	Oxy60	4	3037.61	1866.32	407	1.63	0.1044	0.05	-631.22	6706.45
TRTPN*ATPTN	Oxy30	2	Plac	0	-1579.58	1866.36	407	-0.85	0.3979	0.05	-5248.50	2089.34
TRTPN*ATPTN	Oxy30	2	Plac	0.5	-3159.97	1866.36	407	-1.69	0.0912	0.05	-6828.88	508.95
TRTPN*ATPTN	Oxy30	2	Plac	1	-4049.23	1866.36	407	-2.17	0.0306	0.05	-7718.14	-380.31
TRTPN*ATPTN	Oxy30	2	Plac	2	-243.76	1866.36	407	-0.13	0.8961	0.05	-3912.68	3425.15
TRTPN*ATPTN	Oxy30	2	Plac	3	-45.7422	1866.36	407	-0.02	0.9805	0.05	-3714.66	3623.18
TRTPN*ATPTN	Oxy30	2	Plac	4	-1438.59	1866.36	407	-0.77	0.4413	0.05	-5107.50	2230.33
TRTPN*ATPTN	Oxy30	3	Oxy30	4	-220.75	1864.91	407	-0.12	0.9058	0.05	-3886.82	3445.31
TRTPN*ATPTN	Oxy30	3	Oxy60	0	-585.88	1939.53	407	-0.30	0.7628	0.05	-4398.63	3226.87
TRTPN*ATPTN	Oxy30	3	Oxy60	0.5	1783.96	1939.53	407	0.92	0.3582	0.05	-2028.78	5596.71

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Oxy30	3	Oxy60	1	4079.83	1901.48	407	2.15	0.0325	0.05	341.89	7817.77
TRTPN*ATPTN	Oxy30	3	Oxy60	2	5302.06	1866.32	407	2.84	0.0047	0.05	1633.23	8970.89
TRTPN*ATPTN	Oxy30	3	Oxy60	3	4752.59	1866.32	407	2.55	0.0112	0.05	1083.75	8421.42
TRTPN*ATPTN	Oxy30	3	Oxy60	4	4632.45	1866.32	407	2.48	0.0135	0.05	963.62	8301.28
TRTPN*ATPTN	Oxy30	3	Plac	0	15.2591	1866.36	407	0.01	0.9935	0.05	-3653.66	3684.18
TRTPN*ATPTN	Oxy30	3	Plac	0.5	-1565.13	1866.36	407	-0.84	0.4022	0.05	-5234.05	2103.79
TRTPN*ATPTN	Oxy30	3	Plac	1	-2454.39	1866.36	407	-1.32	0.1892	0.05	-6123.31	1214.53
TRTPN*ATPTN	Oxy30	3	Plac	2	1351.07	1866.36	407	0.72	0.4695	0.05	-2317.84	5019.99
TRTPN*ATPTN	Oxy30	3	Plac	3	1549.10	1866.36	407	0.83	0.4070	0.05	-2119.82	5218.01
TRTPN*ATPTN	Oxy30	3	Plac	4	156.25	1866.36	407	0.08	0.9333	0.05	-3512.67	3825.17
TRTPN*ATPTN	Oxy30	4	Oxy60	0	-365.13	1939.53	407	-0.19	0.8508	0.05	-4177.87	3447.62
TRTPN*ATPTN	Oxy30	4	Oxy60	0.5	2004.72	1939.53	407	1.03	0.3019	0.05	-1808.03	5817.46
TRTPN*ATPTN	Oxy30	4	Oxy60	1	4300.58	1901.48	407	2.26	0.0242	0.05	562.64	8038.52
TRTPN*ATPTN	Oxy30	4	Oxy60	2	5522.81	1866.32	407	2.96	0.0033	0.05	1853.98	9191.64
TRTPN*ATPTN	Oxy30	4	Oxy60	3	4973.34	1866.32	407	2.66	0.0080	0.05	1304.50	8642.17
TRTPN*ATPTN	Oxy30	4	Oxy60	4	4853.20	1866.32	407	2.60	0.0097	0.05	1184.37	8522.04
TRTPN*ATPTN	Oxy30	4	Plac	0	236.01	1866.36	407	0.13	0.8994	0.05	-3432.91	3904.93
TRTPN*ATPTN	Oxy30	4	Plac	0.5	-1344.38	1866.36	407	-0.72	0.4717	0.05	-5013.29	2324.54
TRTPN*ATPTN	Oxy30	4	Plac	1	-2233.63	1866.36	407	-1.20	0.2321	0.05	-5902.55	1435.28
TRTPN*ATPTN	Oxy30	4	Plac	2	1571.83	1866.36	407	0.84	0.4002	0.05	-2097.09	5240.75
TRTPN*ATPTN	Oxy30	4	Plac	3	1769.85	1866.36	407	0.95	0.3435	0.05	-1899.07	5438.77
TRTPN*ATPTN	Oxy30	4	Plac	4	377.01	1866.36	407	0.20	0.8400	0.05	-3291.91	4045.92
TRTPN*ATPTN	Oxy60	0	Oxy60	0.5	2369.84	2003.24	407	1.18	0.2375	0.05	-1568.14	6307.83
TRTPN*ATPTN	Oxy60	0	Oxy60	1	4665.71	1971.54	407	2.37	0.0184	0.05	790.04	8541.38
TRTPN*ATPTN	Oxy60	0	Oxy60	2	5887.94	1937.96	407	3.04	0.0025	0.05	2078.28	9697.60

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Oxy60	0	Oxy60	3	5338.46	1937.96	407	2.75	0.0061	0.05	1528.80	9148.12
TRTPN*ATPTN	Oxy60	0	Oxy60	4	5218.33	1937.96	407	2.69	0.0074	0.05	1408.67	9027.99
TRTPN*ATPTN	Oxy60	0	Plac	0	601.14	1939.56	407	0.31	0.7568	0.05	-3211.67	4413.95
TRTPN*ATPTN	Oxy60	0	Plac	0.5	-979.25	1939.56	407	-0.50	0.6139	0.05	-4792.06	2833.56
TRTPN*ATPTN	Oxy60	0	Plac	1	-1868.51	1939.56	407	-0.96	0.3359	0.05	-5681.32	1944.30
TRTPN*ATPTN	Oxy60	0	Plac	2	1936.95	1939.56	407	1.00	0.3186	0.05	-1875.86	5749.76
TRTPN*ATPTN	Oxy60	0	Plac	3	2134.98	1939.56	407	1.10	0.2717	0.05	-1677.84	5947.79
TRTPN*ATPTN	Oxy60	0	Plac	4	742.13	1939.56	407	0.38	0.7022	0.05	-3070.68	4554.94
TRTPN*ATPTN	Oxy60	0.5	Oxy60	1	2295.86	1971.54	407	1.16	0.2449	0.05	-1579.81	6171.53
TRTPN*ATPTN	Oxy60	0.5	Oxy60	2	3518.09	1937.96	407	1.82	0.0702	0.05	-291.57	7327.75
TRTPN*ATPTN	Oxy60	0.5	Oxy60	3	2968.62	1937.96	407	1.53	0.1263	0.05	-841.04	6778.28
TRTPN*ATPTN	Oxy60	0.5	Oxy60	4	2848.49	1937.96	407	1.47	0.1424	0.05	-961.17	6658.15
TRTPN*ATPTN	Oxy60	0.5	Plac	0	-1768.71	1939.56	407	-0.91	0.3624	0.05	-5581.52	2044.11
TRTPN*ATPTN	Oxy60	0.5	Plac	0.5	-3349.09	1939.56	407	-1.73	0.0850	0.05	-7161.90	463.72
TRTPN*ATPTN	Oxy60	0.5	Plac	1	-4238.35	1939.56	407	-2.19	0.0294	0.05	-8051.16	-425.54
TRTPN*ATPTN	Oxy60	0.5	Plac	2	-432.89	1939.56	407	-0.22	0.8235	0.05	-4245.70	3379.92
TRTPN*ATPTN	Oxy60	0.5	Plac	3	-234.87	1939.56	407	-0.12	0.9037	0.05	-4047.68	3577.94
TRTPN*ATPTN	Oxy60	0.5	Plac	4	-1627.71	1939.56	407	-0.84	0.4018	0.05	-5440.52	2185.10
TRTPN*ATPTN	Oxy60	1	Oxy60	2	1222.23	1899.22	407	0.64	0.5202	0.05	-2511.28	4955.74
TRTPN*ATPTN	Oxy60	1	Oxy60	3	672.76	1899.22	407	0.35	0.7234	0.05	-3060.75	4406.26
TRTPN*ATPTN	Oxy60	1	Oxy60	4	552.62	1899.22	407	0.29	0.7712	0.05	-3180.88	4286.13
TRTPN*ATPTN	Oxy60	1	Plac	0	-4064.57	1900.77	407	-2.14	0.0331	0.05	-7801.13	-328.01
TRTPN*ATPTN	Oxy60	1	Plac	0.5	-5644.96	1900.77	407	-2.97	0.0032	0.05	-9381.52	-1908.39
TRTPN*ATPTN	Oxy60	1	Plac	1	-6534.22	1900.77	407	-3.44	0.0006	0.05	-10271	-2797.65
TRTPN*ATPTN	Oxy60	1	Plac	2	-2728.75	1900.77	407	-1.44	0.1519	0.05	-6465.31	1007.81

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Oxy60	1	Plac	3	-2530.73	1900.77	407	-1.33	0.1838	0.05	-6267.29	1205.83
TRTPN*ATPTN	Oxy60	1	Plac	4	-3923.58	1900.77	407	-2.06	0.0396	0.05	-7660.14	-187.01
TRTPN*ATPTN	Oxy60	2	Oxy60	3	-549.47	1864.91	407	-0.29	0.7684	0.05	-4215.54	3116.59
TRTPN*ATPTN	Oxy60	2	Oxy60	4	-669.61	1864.91	407	-0.36	0.7197	0.05	-4335.67	2996.46
TRTPN*ATPTN	Oxy60	2	Plac	0	-5286.80	1866.36	407	-2.83	0.0048	0.05	-8955.72	-1617.88
TRTPN*ATPTN	Oxy60	2	Plac	0.5	-6867.19	1866.36	407	-3.68	0.0003	0.05	-10536	-3198.27
TRTPN*ATPTN	Oxy60	2	Plac	1	-7756.45	1866.36	407	-4.16	<.0001	0.05	-11425	-4087.53
TRTPN*ATPTN	Oxy60	2	Plac	2	-3950.98	1866.36	407	-2.12	0.0349	0.05	-7619.90	-282.07
TRTPN*ATPTN	Oxy60	2	Plac	3	-3752.96	1866.36	407	-2.01	0.0450	0.05	-7421.88	-84.0457
TRTPN*ATPTN	Oxy60	2	Plac	4	-5145.81	1866.36	407	-2.76	0.0061	0.05	-8814.72	-1476.89
TRTPN*ATPTN	Oxy60	3	Oxy60	4	-120.13	1864.91	407	-0.06	0.9487	0.05	-3786.20	3545.93
TRTPN*ATPTN	Oxy60	3	Plac	0	-4737.33	1866.36	407	-2.54	0.0115	0.05	-8406.24	-1068.41
TRTPN*ATPTN	Oxy60	3	Plac	0.5	-6317.71	1866.36	407	-3.39	0.0008	0.05	-9986.63	-2648.80
TRTPN*ATPTN	Oxy60	3	Plac	1	-7206.97	1866.36	407	-3.86	0.0001	0.05	-10876	-3538.06
TRTPN*ATPTN	Oxy60	3	Plac	2	-3401.51	1866.36	407	-1.82	0.0691	0.05	-7070.43	267.41
TRTPN*ATPTN	Oxy60	3	Plac	3	-3203.49	1866.36	407	-1.72	0.0868	0.05	-6872.41	465.43
TRTPN*ATPTN	Oxy60	3	Plac	4	-4596.33	1866.36	407	-2.46	0.0142	0.05	-8265.25	-927.42
TRTPN*ATPTN	Oxy60	4	Plac	0	-4617.19	1866.36	407	-2.47	0.0138	0.05	-8286.11	-948.27
TRTPN*ATPTN	Oxy60	4	Plac	0.5	-6197.58	1866.36	407	-3.32	0.0010	0.05	-9866.50	-2528.66
TRTPN*ATPTN	Oxy60	4	Plac	1	-7086.84	1866.36	407	-3.80	0.0002	0.05	-10756	-3417.92
TRTPN*ATPTN	Oxy60	4	Plac	2	-3281.38	1866.36	407	-1.76	0.0795	0.05	-6950.29	387.54
TRTPN*ATPTN	Oxy60	4	Plac	3	-3083.35	1866.36	407	-1.65	0.0993	0.05	-6752.27	585.56
TRTPN*ATPTN	Oxy60	4	Plac	4	-4476.20	1866.36	407	-2.40	0.0169	0.05	-8145.12	-807.28
TRTPN*ATPTN	Plac	0	Plac	0.5	-1580.39	1864.91	407	-0.85	0.3973	0.05	-5246.45	2085.68
TRTPN*ATPTN	Plac	0	Plac	1	-2469.65	1864.91	407	-1.32	0.1862	0.05	-6135.71	1196.42

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Plac	0	Plac	2	1335.82	1864.91	407	0.72	0.4742	0.05	-2330.25	5001.88
TRTPN*ATPTN	Plac	0	Plac	3	1533.84	1864.91	407	0.82	0.4113	0.05	-2132.23	5199.90
TRTPN*ATPTN	Plac	0	Plac	4	140.99	1864.91	407	0.08	0.9398	0.05	-3525.07	3807.06
TRTPN*ATPTN	Plac	0.5	Plac	1	-889.26	1864.91	407	-0.48	0.6337	0.05	-4555.32	2776.81
TRTPN*ATPTN	Plac	0.5	Plac	2	2916.20	1864.91	407	1.56	0.1187	0.05	-749.86	6582.27
TRTPN*ATPTN	Plac	0.5	Plac	3	3114.22	1864.91	407	1.67	0.0957	0.05	-551.84	6780.29
TRTPN*ATPTN	Plac	0.5	Plac	4	1721.38	1864.91	407	0.92	0.3565	0.05	-1944.68	5387.45
TRTPN*ATPTN	Plac	1	Plac	2	3805.46	1864.91	407	2.04	0.0419	0.05	139.40	7471.53
TRTPN*ATPTN	Plac	1	Plac	3	4003.48	1864.91	407	2.15	0.0324	0.05	337.42	7669.55
TRTPN*ATPTN	Plac	1	Plac	4	2610.64	1864.91	407	1.40	0.1623	0.05	-1055.43	6276.71
TRTPN*ATPTN	Plac	2	Plac	3	198.02	1864.91	407	0.11	0.9155	0.05	-3468.04	3864.09
TRTPN*ATPTN	Plac	2	Plac	4	-1194.82	1864.91	407	-0.64	0.5221	0.05	-4860.89	2471.24
TRTPN*ATPTN	Plac	3	Plac	4	-1392.84	1864.91	407	-0.75	0.4556	0.05	-5058.91	2273.22

Tests of Effect Slices

Effect	Analysis Timepoint (N)	Num DF	Den DF	F Value	Pr > F
TRTPN*ATPTN	0	5	407	0.54	0.7480
TRTPN*ATPTN	0.5	5	407	2.80	0.0168
TRTPN*ATPTN	1	5	407	3.65	0.0031
TRTPN*ATPTN	2	5	407	2.87	0.0147
TRTPN*ATPTN	3	5	407	1.64	0.1471
TRTPN*ATPTN	4	5	407	1.77	0.1173

Appendix 16.1.9.2.3
Statistical Methods and Analysis Output Supporting Table 14.2.4
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Model Information

Data Set	WORK.ADXV
Dependent Variable	AVAL
Covariance Structure	Compound Symmetry
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Between-Within

Class Level Information

Class	Levels	Values
SUBJID	16	1001 1002 1003 1004 1005 1006 1007 1008 1010 1012 1013 1014 1015 1016 1017 1018
TRTPN	6	Bel300 Bel600 Bel900 Oxy30 Oxy60 Plac
APERIOD	6	P1 P2 P3 P4 P5 P6
ARMCD	6	ABCEDF BEAFCD CADBFE DCFAEB EFBDAC FDECBA
ATPTN	6	0 0.5 1 2 3 4

Dimensions

Covariance Parameters	2
Columns in X	55
Columns in Z	0
Subjects	16
Max Obs per Subject	36

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Number of Observations

Number of Observations Read	545
Number of Observations Used	545
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	10201.54397027	
1	2	10095.46515998	0.00000006
2	1	10095.46488411	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
CS	SUBJID	11371173
Residual		25636473

Fit Statistics

-2 Res Log Likelihood	10095.5
AIC (Smaller is Better)	10099.5
AICC (Smaller is Better)	10099.5
BIC (Smaller is Better)	10101.0

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
1	106.08	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	5	72	7.88	<.0001
APERIOD	5	72	5.82	0.0001
ARMCD	5	10	1.34	0.3239
TRTPN*ATPTN	30	422	2.22	0.0003

Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	0	19956	1566.43	422	12.74	<.0001	0.05	16877	23035
TRTPN*ATPTN	Bel300	0.5	21615	1566.43	422	13.80	<.0001	0.05	18536	24694
TRTPN*ATPTN	Bel300	1	19703	1566.43	422	12.58	<.0001	0.05	16624	22782
TRTPN*ATPTN	Bel300	2	19848	1566.43	422	12.67	<.0001	0.05	16769	22927
TRTPN*ATPTN	Bel300	3	15435	1566.43	422	9.85	<.0001	0.05	12356	18514
TRTPN*ATPTN	Bel300	4	15990	1566.43	422	10.21	<.0001	0.05	12911	19069
TRTPN*ATPTN	Bel600	0	19546	1565.91	422	12.48	<.0001	0.05	16468	22624
TRTPN*ATPTN	Bel600	0.5	20533	1565.91	422	13.11	<.0001	0.05	17455	23611
TRTPN*ATPTN	Bel600	1	19148	1530.53	422	12.51	<.0001	0.05	16140	22156
TRTPN*ATPTN	Bel600	2	17543	1530.53	422	11.46	<.0001	0.05	14534	20551

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel600	3	16703	1530.53	422	10.91	<.0001	0.05	13695	19712
TRTPN*ATPTN	Bel600	4	16887	1530.53	422	11.03	<.0001	0.05	13878	19895
TRTPN*ATPTN	Bel900	0	21316	1605.83	422	13.27	<.0001	0.05	18160	24473
TRTPN*ATPTN	Bel900	0.5	22751	1566.65	422	14.52	<.0001	0.05	19672	25831
TRTPN*ATPTN	Bel900	1	19932	1566.65	422	12.72	<.0001	0.05	16852	23011
TRTPN*ATPTN	Bel900	2	18174	1566.65	422	11.60	<.0001	0.05	15094	21253
TRTPN*ATPTN	Bel900	3	17494	1566.65	422	11.17	<.0001	0.05	14414	20573
TRTPN*ATPTN	Bel900	4	16445	1566.65	422	10.50	<.0001	0.05	13366	19525
TRTPN*ATPTN	Oxy30	0	20087	1651.59	422	12.16	<.0001	0.05	16841	23334
TRTPN*ATPTN	Oxy30	0.5	17815	1651.59	422	10.79	<.0001	0.05	14569	21061
TRTPN*ATPTN	Oxy30	1	15960	1606.15	422	9.94	<.0001	0.05	12803	19117
TRTPN*ATPTN	Oxy30	2	16815	1566.67	422	10.73	<.0001	0.05	13736	19895
TRTPN*ATPTN	Oxy30	3	18410	1566.67	422	11.75	<.0001	0.05	15331	21490
TRTPN*ATPTN	Oxy30	4	18631	1566.67	422	11.89	<.0001	0.05	15552	21711
TRTPN*ATPTN	Oxy60	0	18627	1607.20	422	11.59	<.0001	0.05	15468	21786
TRTPN*ATPTN	Oxy60	0.5	16395	1607.20	422	10.20	<.0001	0.05	13236	19554
TRTPN*ATPTN	Oxy60	1	14303	1567.67	422	9.12	<.0001	0.05	11222	17385
TRTPN*ATPTN	Oxy60	2	13311	1530.56	422	8.70	<.0001	0.05	10302	16319
TRTPN*ATPTN	Oxy60	3	13978	1530.56	422	9.13	<.0001	0.05	10969	16986
TRTPN*ATPTN	Oxy60	4	14097	1530.56	422	9.21	<.0001	0.05	11088	17105
TRTPN*ATPTN	Plac	0	18495	1530.50	422	12.08	<.0001	0.05	15487	21503
TRTPN*ATPTN	Plac	0.5	20021	1530.50	422	13.08	<.0001	0.05	17012	23029
TRTPN*ATPTN	Plac	1	20972	1530.50	422	13.70	<.0001	0.05	17964	23981
TRTPN*ATPTN	Plac	2	16906	1530.50	422	11.05	<.0001	0.05	13897	19914

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Plac	3	17320	1530.50	422	11.32	<.0001	0.05	14312	20328
TRTPN*ATPTN	Plac	4	18499	1530.50	422	12.09	<.0001	0.05	15491	21508

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	0	Bel300	0.5	-1659.32	1848.84	422	-0.90	0.3700	0.05	-5293.40	1974.75
TRTPN*ATPTN	Bel300	0	Bel300	1	252.85	1848.84	422	0.14	0.8913	0.05	-3381.22	3886.93
TRTPN*ATPTN	Bel300	0	Bel300	2	108.37	1848.84	422	0.06	0.9533	0.05	-3525.71	3742.44
TRTPN*ATPTN	Bel300	0	Bel300	3	4521.35	1848.84	422	2.45	0.0149	0.05	887.28	8155.43
TRTPN*ATPTN	Bel300	0	Bel300	4	3966.17	1848.84	422	2.15	0.0325	0.05	332.10	7600.25
TRTPN*ATPTN	Bel300	0	Bel600	0	410.18	1852.53	422	0.22	0.8249	0.05	-3231.15	4051.51
TRTPN*ATPTN	Bel300	0	Bel600	0.5	-576.54	1852.53	422	-0.31	0.7558	0.05	-4217.87	3064.79
TRTPN*ATPTN	Bel300	0	Bel600	1	808.09	1822.76	422	0.44	0.6578	0.05	-2774.72	4390.90
TRTPN*ATPTN	Bel300	0	Bel600	2	2413.31	1822.76	422	1.32	0.1862	0.05	-1169.50	5996.12
TRTPN*ATPTN	Bel300	0	Bel600	3	3252.96	1822.76	422	1.78	0.0750	0.05	-329.85	6835.77
TRTPN*ATPTN	Bel300	0	Bel600	4	3069.51	1822.76	422	1.68	0.0929	0.05	-513.30	6652.32
TRTPN*ATPTN	Bel300	0	Bel900	0	-1360.31	1883.44	422	-0.72	0.4705	0.05	-5062.40	2341.78
TRTPN*ATPTN	Bel300	0	Bel900	0.5	-2794.98	1850.18	422	-1.51	0.1316	0.05	-6431.69	841.73
TRTPN*ATPTN	Bel300	0	Bel900	1	24.4926	1850.18	422	0.01	0.9894	0.05	-3612.22	3661.20
TRTPN*ATPTN	Bel300	0	Bel900	2	1782.25	1850.18	422	0.96	0.3360	0.05	-1854.46	5418.96
TRTPN*ATPTN	Bel300	0	Bel900	3	2462.51	1850.18	422	1.33	0.1839	0.05	-1174.20	6099.22
TRTPN*ATPTN	Bel300	0	Bel900	4	3511.00	1850.18	422	1.90	0.0584	0.05	-125.71	7147.71

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	0	Oxy30	0	-131.08	1922.13	422	-0.07	0.9457	0.05	-3909.22	3647.07
TRTPN*ATPTN	Bel300	0	Oxy30	0.5	2141.07	1922.13	422	1.11	0.2660	0.05	-1637.08	5919.22
TRTPN*ATPTN	Bel300	0	Oxy30	1	3995.79	1883.53	422	2.12	0.0345	0.05	293.52	7698.06
TRTPN*ATPTN	Bel300	0	Oxy30	2	3140.64	1850.26	422	1.70	0.0904	0.05	-496.23	6777.51
TRTPN*ATPTN	Bel300	0	Oxy30	3	1545.80	1850.26	422	0.84	0.4039	0.05	-2091.07	5182.67
TRTPN*ATPTN	Bel300	0	Oxy30	4	1325.05	1850.26	422	0.72	0.4743	0.05	-2311.82	4961.92
TRTPN*ATPTN	Bel300	0	Oxy60	0	1329.04	1886.80	422	0.70	0.4816	0.05	-2379.67	5037.74
TRTPN*ATPTN	Bel300	0	Oxy60	0.5	3561.27	1886.80	422	1.89	0.0598	0.05	-147.43	7269.97
TRTPN*ATPTN	Bel300	0	Oxy60	1	5652.80	1852.83	422	3.05	0.0024	0.05	2010.86	9294.73
TRTPN*ATPTN	Bel300	0	Oxy60	2	6645.35	1822.14	422	3.65	0.0003	0.05	3063.75	10227
TRTPN*ATPTN	Bel300	0	Oxy60	3	5978.53	1822.14	422	3.28	0.0011	0.05	2396.93	9560.13
TRTPN*ATPTN	Bel300	0	Oxy60	4	5859.39	1822.14	422	3.22	0.0014	0.05	2277.79	9440.99
TRTPN*ATPTN	Bel300	0	Plac	0	1461.12	1821.91	422	0.80	0.4230	0.05	-2120.03	5042.26
TRTPN*ATPTN	Bel300	0	Plac	0.5	-64.5111	1821.91	422	-0.04	0.9718	0.05	-3645.65	3516.63
TRTPN*ATPTN	Bel300	0	Plac	1	-1016.01	1821.91	422	-0.56	0.5774	0.05	-4597.16	2565.13
TRTPN*ATPTN	Bel300	0	Plac	2	3050.29	1821.91	422	1.67	0.0948	0.05	-530.86	6631.43
TRTPN*ATPTN	Bel300	0	Plac	3	2636.22	1821.91	422	1.45	0.1487	0.05	-944.92	6217.36
TRTPN*ATPTN	Bel300	0	Plac	4	1456.98	1821.91	422	0.80	0.4243	0.05	-2124.16	5038.13
TRTPN*ATPTN	Bel300	0.5	Bel300	1	1912.18	1848.84	422	1.03	0.3016	0.05	-1721.90	5546.25
TRTPN*ATPTN	Bel300	0.5	Bel300	2	1767.69	1848.84	422	0.96	0.3396	0.05	-1866.39	5401.76
TRTPN*ATPTN	Bel300	0.5	Bel300	3	6180.67	1848.84	422	3.34	0.0009	0.05	2546.60	9814.75
TRTPN*ATPTN	Bel300	0.5	Bel300	4	5625.50	1848.84	422	3.04	0.0025	0.05	1991.42	9259.57
TRTPN*ATPTN	Bel300	0.5	Bel600	0	2069.50	1852.53	422	1.12	0.2646	0.05	-1571.83	5710.83
TRTPN*ATPTN	Bel300	0.5	Bel600	0.5	1082.78	1852.53	422	0.58	0.5592	0.05	-2558.55	4724.11
TRTPN*ATPTN	Bel300	0.5	Bel600	1	2467.41	1822.76	422	1.35	0.1766	0.05	-1115.40	6050.22

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	0.5	Bel600	2	4072.63	1822.76	422	2.23	0.0260	0.05	489.82	7655.44
TRTPN*ATPTN	Bel300	0.5	Bel600	3	4912.28	1822.76	422	2.69	0.0073	0.05	1329.47	8495.09
TRTPN*ATPTN	Bel300	0.5	Bel600	4	4728.84	1822.76	422	2.59	0.0098	0.05	1146.03	8311.65
TRTPN*ATPTN	Bel300	0.5	Bel900	0	299.01	1883.44	422	0.16	0.8739	0.05	-3403.08	4001.10
TRTPN*ATPTN	Bel300	0.5	Bel900	0.5	-1135.66	1850.18	422	-0.61	0.5397	0.05	-4772.37	2501.05
TRTPN*ATPTN	Bel300	0.5	Bel900	1	1683.81	1850.18	422	0.91	0.3633	0.05	-1952.89	5320.52
TRTPN*ATPTN	Bel300	0.5	Bel900	2	3441.57	1850.18	422	1.86	0.0636	0.05	-195.14	7078.28
TRTPN*ATPTN	Bel300	0.5	Bel900	3	4121.83	1850.18	422	2.23	0.0264	0.05	485.12	7758.54
TRTPN*ATPTN	Bel300	0.5	Bel900	4	5170.32	1850.18	422	2.79	0.0054	0.05	1533.61	8807.03
TRTPN*ATPTN	Bel300	0.5	Oxy30	0	1528.24	1922.13	422	0.80	0.4270	0.05	-2249.90	5306.39
TRTPN*ATPTN	Bel300	0.5	Oxy30	0.5	3800.39	1922.13	422	1.98	0.0487	0.05	22.2455	7578.54
TRTPN*ATPTN	Bel300	0.5	Oxy30	1	5655.11	1883.53	422	3.00	0.0028	0.05	1952.84	9357.38
TRTPN*ATPTN	Bel300	0.5	Oxy30	2	4799.96	1850.26	422	2.59	0.0098	0.05	1163.09	8436.83
TRTPN*ATPTN	Bel300	0.5	Oxy30	3	3205.12	1850.26	422	1.73	0.0840	0.05	-431.74	6841.99
TRTPN*ATPTN	Bel300	0.5	Oxy30	4	2984.37	1850.26	422	1.61	0.1075	0.05	-652.50	6621.24
TRTPN*ATPTN	Bel300	0.5	Oxy60	0	2988.36	1886.80	422	1.58	0.1140	0.05	-720.34	6697.06
TRTPN*ATPTN	Bel300	0.5	Oxy60	0.5	5220.59	1886.80	422	2.77	0.0059	0.05	1511.89	8929.29
TRTPN*ATPTN	Bel300	0.5	Oxy60	1	7312.12	1852.83	422	3.95	<.0001	0.05	3670.18	10954
TRTPN*ATPTN	Bel300	0.5	Oxy60	2	8304.67	1822.14	422	4.56	<.0001	0.05	4723.07	11886
TRTPN*ATPTN	Bel300	0.5	Oxy60	3	7637.85	1822.14	422	4.19	<.0001	0.05	4056.25	11219
TRTPN*ATPTN	Bel300	0.5	Oxy60	4	7518.71	1822.14	422	4.13	<.0001	0.05	3937.11	11100
TRTPN*ATPTN	Bel300	0.5	Plac	0	3120.44	1821.91	422	1.71	0.0875	0.05	-460.71	6701.58
TRTPN*ATPTN	Bel300	0.5	Plac	0.5	1594.81	1821.91	422	0.88	0.3819	0.05	-1986.33	5175.95
TRTPN*ATPTN	Bel300	0.5	Plac	1	643.31	1821.91	422	0.35	0.7242	0.05	-2937.84	4224.45
TRTPN*ATPTN	Bel300	0.5	Plac	2	4709.61	1821.91	422	2.58	0.0101	0.05	1128.46	8290.75

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	0.5	Plac	3	4295.54	1821.91	422	2.36	0.0188	0.05	714.40	7876.68
TRTPN*ATPTN	Bel300	0.5	Plac	4	3116.30	1821.91	422	1.71	0.0879	0.05	-464.84	6697.45
TRTPN*ATPTN	Bel300	1	Bel300	2	-144.49	1848.84	422	-0.08	0.9377	0.05	-3778.57	3489.59
TRTPN*ATPTN	Bel300	1	Bel300	3	4268.50	1848.84	422	2.31	0.0214	0.05	634.42	7902.57
TRTPN*ATPTN	Bel300	1	Bel300	4	3713.32	1848.84	422	2.01	0.0452	0.05	79.2444	7347.40
TRTPN*ATPTN	Bel300	1	Bel600	0	157.33	1852.53	422	0.08	0.9324	0.05	-3484.00	3798.66
TRTPN*ATPTN	Bel300	1	Bel600	0.5	-829.40	1852.53	422	-0.45	0.6546	0.05	-4470.73	2811.94
TRTPN*ATPTN	Bel300	1	Bel600	1	555.23	1822.76	422	0.30	0.7608	0.05	-3027.58	4138.04
TRTPN*ATPTN	Bel300	1	Bel600	2	2160.46	1822.76	422	1.19	0.2366	0.05	-1422.35	5743.27
TRTPN*ATPTN	Bel300	1	Bel600	3	3000.10	1822.76	422	1.65	0.1005	0.05	-582.71	6582.91
TRTPN*ATPTN	Bel300	1	Bel600	4	2816.66	1822.76	422	1.55	0.1230	0.05	-766.15	6399.47
TRTPN*ATPTN	Bel300	1	Bel900	0	-1613.16	1883.44	422	-0.86	0.3922	0.05	-5315.25	2088.92
TRTPN*ATPTN	Bel300	1	Bel900	0.5	-3047.84	1850.18	422	-1.65	0.1002	0.05	-6684.54	588.87
TRTPN*ATPTN	Bel300	1	Bel900	1	-228.36	1850.18	422	-0.12	0.9018	0.05	-3865.07	3408.35
TRTPN*ATPTN	Bel300	1	Bel900	2	1529.39	1850.18	422	0.83	0.4089	0.05	-2107.32	5166.10
TRTPN*ATPTN	Bel300	1	Bel900	3	2209.66	1850.18	422	1.19	0.2330	0.05	-1427.05	5846.36
TRTPN*ATPTN	Bel300	1	Bel900	4	3258.15	1850.18	422	1.76	0.0790	0.05	-378.56	6894.85
TRTPN*ATPTN	Bel300	1	Oxy30	0	-383.93	1922.13	422	-0.20	0.8418	0.05	-4162.08	3394.21
TRTPN*ATPTN	Bel300	1	Oxy30	0.5	1888.22	1922.13	422	0.98	0.3265	0.05	-1889.93	5666.36
TRTPN*ATPTN	Bel300	1	Oxy30	1	3742.94	1883.53	422	1.99	0.0475	0.05	40.6684	7445.20
TRTPN*ATPTN	Bel300	1	Oxy30	2	2887.79	1850.26	422	1.56	0.1193	0.05	-749.08	6524.65
TRTPN*ATPTN	Bel300	1	Oxy30	3	1292.95	1850.26	422	0.70	0.4851	0.05	-2343.92	4929.82
TRTPN*ATPTN	Bel300	1	Oxy30	4	1072.20	1850.26	422	0.58	0.5626	0.05	-2564.67	4709.06
TRTPN*ATPTN	Bel300	1	Oxy60	0	1076.18	1886.80	422	0.57	0.5687	0.05	-2632.52	4784.88
TRTPN*ATPTN	Bel300	1	Oxy60	0.5	3308.42	1886.80	422	1.75	0.0803	0.05	-400.29	7017.12

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	1	Oxy60	1	5399.94	1852.83	422	2.91	0.0038	0.05	1758.01	9041.88
TRTPN*ATPTN	Bel300	1	Oxy60	2	6392.49	1822.14	422	3.51	0.0005	0.05	2810.89	9974.09
TRTPN*ATPTN	Bel300	1	Oxy60	3	5725.68	1822.14	422	3.14	0.0018	0.05	2144.08	9307.28
TRTPN*ATPTN	Bel300	1	Oxy60	4	5606.54	1822.14	422	3.08	0.0022	0.05	2024.94	9188.14
TRTPN*ATPTN	Bel300	1	Plac	0	1208.26	1821.91	422	0.66	0.5076	0.05	-2372.88	4789.40
TRTPN*ATPTN	Bel300	1	Plac	0.5	-317.37	1821.91	422	-0.17	0.8618	0.05	-3898.51	3263.78
TRTPN*ATPTN	Bel300	1	Plac	1	-1268.87	1821.91	422	-0.70	0.4865	0.05	-4850.01	2312.27
TRTPN*ATPTN	Bel300	1	Plac	2	2797.43	1821.91	422	1.54	0.1254	0.05	-783.71	6378.57
TRTPN*ATPTN	Bel300	1	Plac	3	2383.36	1821.91	422	1.31	0.1915	0.05	-1197.78	5964.50
TRTPN*ATPTN	Bel300	1	Plac	4	1204.13	1821.91	422	0.66	0.5090	0.05	-2377.01	4785.27
TRTPN*ATPTN	Bel300	2	Bel300	3	4412.99	1848.84	422	2.39	0.0174	0.05	778.91	8047.06
TRTPN*ATPTN	Bel300	2	Bel300	4	3857.81	1848.84	422	2.09	0.0375	0.05	223.73	7491.89
TRTPN*ATPTN	Bel300	2	Bel600	0	301.82	1852.53	422	0.16	0.8707	0.05	-3339.51	3943.15
TRTPN*ATPTN	Bel300	2	Bel600	0.5	-684.91	1852.53	422	-0.37	0.7118	0.05	-4326.24	2956.43
TRTPN*ATPTN	Bel300	2	Bel600	1	699.72	1822.76	422	0.38	0.7013	0.05	-2883.09	4282.53
TRTPN*ATPTN	Bel300	2	Bel600	2	2304.95	1822.76	422	1.26	0.2067	0.05	-1277.86	5887.76
TRTPN*ATPTN	Bel300	2	Bel600	3	3144.59	1822.76	422	1.73	0.0852	0.05	-438.22	6727.40
TRTPN*ATPTN	Bel300	2	Bel600	4	2961.15	1822.76	422	1.62	0.1050	0.05	-621.66	6543.96
TRTPN*ATPTN	Bel300	2	Bel900	0	-1468.68	1883.44	422	-0.78	0.4360	0.05	-5170.76	2233.41
TRTPN*ATPTN	Bel300	2	Bel900	0.5	-2903.35	1850.18	422	-1.57	0.1173	0.05	-6540.05	733.36
TRTPN*ATPTN	Bel300	2	Bel900	1	-83.8725	1850.18	422	-0.05	0.9639	0.05	-3720.58	3552.84
TRTPN*ATPTN	Bel300	2	Bel900	2	1673.88	1850.18	422	0.90	0.3661	0.05	-1962.83	5310.59
TRTPN*ATPTN	Bel300	2	Bel900	3	2354.15	1850.18	422	1.27	0.2039	0.05	-1282.56	5990.85
TRTPN*ATPTN	Bel300	2	Bel900	4	3402.64	1850.18	422	1.84	0.0666	0.05	-234.07	7039.34
TRTPN*ATPTN	Bel300	2	Oxy30	0	-239.44	1922.13	422	-0.12	0.9009	0.05	-4017.59	3538.70

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	2	Oxy30	0.5	2032.71	1922.13	422	1.06	0.2909	0.05	-1745.44	5810.85
TRTPN*ATPTN	Bel300	2	Oxy30	1	3887.43	1883.53	422	2.06	0.0396	0.05	185.16	7589.69
TRTPN*ATPTN	Bel300	2	Oxy30	2	3032.28	1850.26	422	1.64	0.1020	0.05	-604.59	6669.14
TRTPN*ATPTN	Bel300	2	Oxy30	3	1437.44	1850.26	422	0.78	0.4377	0.05	-2199.43	5074.31
TRTPN*ATPTN	Bel300	2	Oxy30	4	1216.68	1850.26	422	0.66	0.5112	0.05	-2420.18	4853.55
TRTPN*ATPTN	Bel300	2	Oxy60	0	1220.67	1886.80	422	0.65	0.5180	0.05	-2488.03	4929.37
TRTPN*ATPTN	Bel300	2	Oxy60	0.5	3452.91	1886.80	422	1.83	0.0680	0.05	-255.80	7161.61
TRTPN*ATPTN	Bel300	2	Oxy60	1	5544.43	1852.83	422	2.99	0.0029	0.05	1902.50	9186.37
TRTPN*ATPTN	Bel300	2	Oxy60	2	6536.98	1822.14	422	3.59	0.0004	0.05	2955.38	10119
TRTPN*ATPTN	Bel300	2	Oxy60	3	5870.17	1822.14	422	3.22	0.0014	0.05	2288.57	9451.77
TRTPN*ATPTN	Bel300	2	Oxy60	4	5751.03	1822.14	422	3.16	0.0017	0.05	2169.43	9332.63
TRTPN*ATPTN	Bel300	2	Plac	0	1352.75	1821.91	422	0.74	0.4582	0.05	-2228.39	4933.89
TRTPN*ATPTN	Bel300	2	Plac	0.5	-172.88	1821.91	422	-0.09	0.9244	0.05	-3754.02	3408.27
TRTPN*ATPTN	Bel300	2	Plac	1	-1124.38	1821.91	422	-0.62	0.5375	0.05	-4705.52	2456.76
TRTPN*ATPTN	Bel300	2	Plac	2	2941.92	1821.91	422	1.61	0.1071	0.05	-639.22	6523.06
TRTPN*ATPTN	Bel300	2	Plac	3	2527.85	1821.91	422	1.39	0.1660	0.05	-1053.29	6108.99
TRTPN*ATPTN	Bel300	2	Plac	4	1348.62	1821.91	422	0.74	0.4596	0.05	-2232.52	4929.76
TRTPN*ATPTN	Bel300	3	Bel300	4	-555.18	1848.84	422	-0.30	0.7641	0.05	-4189.25	3078.90
TRTPN*ATPTN	Bel300	3	Bel600	0	-4111.17	1852.53	422	-2.22	0.0270	0.05	-7752.50	-469.84
TRTPN*ATPTN	Bel300	3	Bel600	0.5	-5097.89	1852.53	422	-2.75	0.0062	0.05	-8739.22	-1456.56
TRTPN*ATPTN	Bel300	3	Bel600	1	-3713.27	1822.76	422	-2.04	0.0423	0.05	-7296.08	-130.46
TRTPN*ATPTN	Bel300	3	Bel600	2	-2108.04	1822.76	422	-1.16	0.2481	0.05	-5690.85	1474.77
TRTPN*ATPTN	Bel300	3	Bel600	3	-1268.39	1822.76	422	-0.70	0.4869	0.05	-4851.20	2314.42
TRTPN*ATPTN	Bel300	3	Bel600	4	-1451.84	1822.76	422	-0.80	0.4262	0.05	-5034.65	2130.97
TRTPN*ATPTN	Bel300	3	Bel900	0	-5881.66	1883.44	422	-3.12	0.0019	0.05	-9583.75	-2179.57

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	3	Bel900	0.5	-7316.33	1850.18	422	-3.95	<.0001	0.05	-10953	-3679.63
TRTPN*ATPTN	Bel300	3	Bel900	1	-4496.86	1850.18	422	-2.43	0.0155	0.05	-8133.57	-860.15
TRTPN*ATPTN	Bel300	3	Bel900	2	-2739.11	1850.18	422	-1.48	0.1395	0.05	-6375.81	897.60
TRTPN*ATPTN	Bel300	3	Bel900	3	-2058.84	1850.18	422	-1.11	0.2664	0.05	-5695.55	1577.87
TRTPN*ATPTN	Bel300	3	Bel900	4	-1010.35	1850.18	422	-0.55	0.5853	0.05	-4647.06	2626.36
TRTPN*ATPTN	Bel300	3	Oxy30	0	-4652.43	1922.13	422	-2.42	0.0159	0.05	-8430.58	-874.28
TRTPN*ATPTN	Bel300	3	Oxy30	0.5	-2380.28	1922.13	422	-1.24	0.2163	0.05	-6158.43	1397.86
TRTPN*ATPTN	Bel300	3	Oxy30	1	-525.56	1883.53	422	-0.28	0.7804	0.05	-4227.83	3176.71
TRTPN*ATPTN	Bel300	3	Oxy30	2	-1380.71	1850.26	422	-0.75	0.4559	0.05	-5017.58	2256.16
TRTPN*ATPTN	Bel300	3	Oxy30	3	-2975.55	1850.26	422	-1.61	0.1085	0.05	-6612.42	661.32
TRTPN*ATPTN	Bel300	3	Oxy30	4	-3196.30	1850.26	422	-1.73	0.0848	0.05	-6833.17	440.57
TRTPN*ATPTN	Bel300	3	Oxy60	0	-3192.32	1886.80	422	-1.69	0.0914	0.05	-6901.02	516.39
TRTPN*ATPTN	Bel300	3	Oxy60	0.5	-960.08	1886.80	422	-0.51	0.6111	0.05	-4668.78	2748.62
TRTPN*ATPTN	Bel300	3	Oxy60	1	1131.44	1852.83	422	0.61	0.5418	0.05	-2510.49	4773.38
TRTPN*ATPTN	Bel300	3	Oxy60	2	2124.00	1822.14	422	1.17	0.2444	0.05	-1457.60	5705.59
TRTPN*ATPTN	Bel300	3	Oxy60	3	1457.18	1822.14	422	0.80	0.4243	0.05	-2124.42	5038.78
TRTPN*ATPTN	Bel300	3	Oxy60	4	1338.04	1822.14	422	0.73	0.4632	0.05	-2243.56	4919.64
TRTPN*ATPTN	Bel300	3	Plac	0	-3060.24	1821.91	422	-1.68	0.0938	0.05	-6641.38	520.90
TRTPN*ATPTN	Bel300	3	Plac	0.5	-4585.86	1821.91	422	-2.52	0.0122	0.05	-8167.01	-1004.72
TRTPN*ATPTN	Bel300	3	Plac	1	-5537.37	1821.91	422	-3.04	0.0025	0.05	-9118.51	-1956.22
TRTPN*ATPTN	Bel300	3	Plac	2	-1471.07	1821.91	422	-0.81	0.4199	0.05	-5052.21	2110.08
TRTPN*ATPTN	Bel300	3	Plac	3	-1885.14	1821.91	422	-1.03	0.3014	0.05	-5466.28	1696.01
TRTPN*ATPTN	Bel300	3	Plac	4	-3064.37	1821.91	422	-1.68	0.0933	0.05	-6645.51	516.77
TRTPN*ATPTN	Bel300	4	Bel600	0	-3555.99	1852.53	422	-1.92	0.0556	0.05	-7197.32	85.3376
TRTPN*ATPTN	Bel300	4	Bel600	0.5	-4542.71	1852.53	422	-2.45	0.0146	0.05	-8184.05	-901.38

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	4	Bel600	1	-3158.09	1822.76	422	-1.73	0.0839	0.05	-6740.90	424.72
TRTPN*ATPTN	Bel300	4	Bel600	2	-1552.86	1822.76	422	-0.85	0.3947	0.05	-5135.67	2029.95
TRTPN*ATPTN	Bel300	4	Bel600	3	-713.22	1822.76	422	-0.39	0.6958	0.05	-4296.03	2869.59
TRTPN*ATPTN	Bel300	4	Bel600	4	-896.66	1822.76	422	-0.49	0.6230	0.05	-4479.47	2686.15
TRTPN*ATPTN	Bel300	4	Bel900	0	-5326.48	1883.44	422	-2.83	0.0049	0.05	-9028.57	-1624.40
TRTPN*ATPTN	Bel300	4	Bel900	0.5	-6761.16	1850.18	422	-3.65	0.0003	0.05	-10398	-3124.45
TRTPN*ATPTN	Bel300	4	Bel900	1	-3941.68	1850.18	422	-2.13	0.0337	0.05	-7578.39	-304.97
TRTPN*ATPTN	Bel300	4	Bel900	2	-2183.93	1850.18	422	-1.18	0.2385	0.05	-5820.64	1452.78
TRTPN*ATPTN	Bel300	4	Bel900	3	-1503.66	1850.18	422	-0.81	0.4168	0.05	-5140.37	2133.04
TRTPN*ATPTN	Bel300	4	Bel900	4	-455.17	1850.18	422	-0.25	0.8058	0.05	-4091.88	3181.53
TRTPN*ATPTN	Bel300	4	Oxy30	0	-4097.25	1922.13	422	-2.13	0.0336	0.05	-7875.40	-319.11
TRTPN*ATPTN	Bel300	4	Oxy30	0.5	-1825.10	1922.13	422	-0.95	0.3429	0.05	-5603.25	1953.04
TRTPN*ATPTN	Bel300	4	Oxy30	1	29.6164	1883.53	422	0.02	0.9875	0.05	-3672.65	3731.88
TRTPN*ATPTN	Bel300	4	Oxy30	2	-825.53	1850.26	422	-0.45	0.6557	0.05	-4462.40	2811.33
TRTPN*ATPTN	Bel300	4	Oxy30	3	-2420.37	1850.26	422	-1.31	0.1915	0.05	-6057.24	1216.50
TRTPN*ATPTN	Bel300	4	Oxy30	4	-2641.12	1850.26	422	-1.43	0.1542	0.05	-6277.99	995.74
TRTPN*ATPTN	Bel300	4	Oxy60	0	-2637.14	1886.80	422	-1.40	0.1629	0.05	-6345.84	1071.56
TRTPN*ATPTN	Bel300	4	Oxy60	0.5	-404.90	1886.80	422	-0.21	0.8302	0.05	-4113.61	3303.80
TRTPN*ATPTN	Bel300	4	Oxy60	1	1686.62	1852.83	422	0.91	0.3632	0.05	-1955.31	5328.56
TRTPN*ATPTN	Bel300	4	Oxy60	2	2679.17	1822.14	422	1.47	0.1422	0.05	-902.43	6260.77
TRTPN*ATPTN	Bel300	4	Oxy60	3	2012.36	1822.14	422	1.10	0.2701	0.05	-1569.24	5593.96
TRTPN*ATPTN	Bel300	4	Oxy60	4	1893.22	1822.14	422	1.04	0.2994	0.05	-1688.38	5474.82
TRTPN*ATPTN	Bel300	4	Plac	0	-2505.06	1821.91	422	-1.37	0.1699	0.05	-6086.20	1076.08
TRTPN*ATPTN	Bel300	4	Plac	0.5	-4030.69	1821.91	422	-2.21	0.0275	0.05	-7611.83	-449.54
TRTPN*ATPTN	Bel300	4	Plac	1	-4982.19	1821.91	422	-2.73	0.0065	0.05	-8563.33	-1401.05

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel300	4	Plac	2	-915.89	1821.91	422	-0.50	0.6154	0.05	-4497.03	2665.25
TRTPN*ATPTN	Bel300	4	Plac	3	-1329.96	1821.91	422	-0.73	0.4658	0.05	-4911.10	2251.18
TRTPN*ATPTN	Bel300	4	Plac	4	-2509.19	1821.91	422	-1.38	0.1692	0.05	-6090.33	1071.95
TRTPN*ATPTN	Bel600	0	Bel600	0.5	-986.72	1848.84	422	-0.53	0.5938	0.05	-4620.80	2647.35
TRTPN*ATPTN	Bel600	0	Bel600	1	397.90	1820.87	422	0.22	0.8271	0.05	-3181.21	3977.02
TRTPN*ATPTN	Bel600	0	Bel600	2	2003.13	1820.87	422	1.10	0.2719	0.05	-1575.98	5582.24
TRTPN*ATPTN	Bel600	0	Bel600	3	2842.78	1820.87	422	1.56	0.1192	0.05	-736.34	6421.89
TRTPN*ATPTN	Bel600	0	Bel600	4	2659.33	1820.87	422	1.46	0.1449	0.05	-919.78	6238.45
TRTPN*ATPTN	Bel600	0	Bel900	0	-1770.49	1886.03	422	-0.94	0.3484	0.05	-5477.67	1936.69
TRTPN*ATPTN	Bel600	0	Bel900	0.5	-3205.16	1852.11	422	-1.73	0.0843	0.05	-6845.67	435.35
TRTPN*ATPTN	Bel600	0	Bel900	1	-385.69	1852.11	422	-0.21	0.8351	0.05	-4026.20	3254.82
TRTPN*ATPTN	Bel600	0	Bel900	2	1372.07	1852.11	422	0.74	0.4592	0.05	-2268.44	5012.57
TRTPN*ATPTN	Bel600	0	Bel900	3	2052.33	1852.11	422	1.11	0.2684	0.05	-1588.18	5692.84
TRTPN*ATPTN	Bel600	0	Bel900	4	3100.82	1852.11	422	1.67	0.0948	0.05	-539.69	6741.33
TRTPN*ATPTN	Bel600	0	Oxy30	0	-541.26	1925.09	422	-0.28	0.7787	0.05	-4325.21	3242.69
TRTPN*ATPTN	Bel600	0	Oxy30	0.5	1730.89	1925.09	422	0.90	0.3691	0.05	-2053.06	5514.84
TRTPN*ATPTN	Bel600	0	Oxy30	1	3585.61	1886.28	422	1.90	0.0580	0.05	-122.07	7293.29
TRTPN*ATPTN	Bel600	0	Oxy30	2	2730.46	1852.82	422	1.47	0.1413	0.05	-911.45	6372.37
TRTPN*ATPTN	Bel600	0	Oxy30	3	1135.62	1852.82	422	0.61	0.5403	0.05	-2506.29	4777.53
TRTPN*ATPTN	Bel600	0	Oxy30	4	914.87	1852.82	422	0.49	0.6217	0.05	-2727.04	4556.78
TRTPN*ATPTN	Bel600	0	Oxy60	0	918.86	1886.96	422	0.49	0.6265	0.05	-2790.16	4627.87
TRTPN*ATPTN	Bel600	0	Oxy60	0.5	3151.09	1886.96	422	1.67	0.0957	0.05	-557.92	6860.11
TRTPN*ATPTN	Bel600	0	Oxy60	1	5242.62	1853.41	422	2.83	0.0049	0.05	1599.55	8885.68
TRTPN*ATPTN	Bel600	0	Oxy60	2	6235.17	1822.19	422	3.42	0.0007	0.05	2653.47	9816.86
TRTPN*ATPTN	Bel600	0	Oxy60	3	5568.35	1822.19	422	3.06	0.0024	0.05	1986.66	9150.05

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel600	0	Oxy60	4	5449.21	1822.19	422	2.99	0.0029	0.05	1867.52	9030.91
TRTPN*ATPTN	Bel600	0	Plac	0	1050.93	1820.82	422	0.58	0.5641	0.05	-2528.08	4629.94
TRTPN*ATPTN	Bel600	0	Plac	0.5	-474.69	1820.82	422	-0.26	0.7944	0.05	-4053.70	3104.32
TRTPN*ATPTN	Bel600	0	Plac	1	-1426.19	1820.82	422	-0.78	0.4339	0.05	-5005.20	2152.81
TRTPN*ATPTN	Bel600	0	Plac	2	2640.11	1820.82	422	1.45	0.1478	0.05	-938.90	6219.11
TRTPN*ATPTN	Bel600	0	Plac	3	2226.04	1820.82	422	1.22	0.2222	0.05	-1352.97	5805.05
TRTPN*ATPTN	Bel600	0	Plac	4	1046.80	1820.82	422	0.57	0.5657	0.05	-2532.21	4625.81
TRTPN*ATPTN	Bel600	0.5	Bel600	1	1384.63	1820.87	422	0.76	0.4474	0.05	-2194.49	4963.74
TRTPN*ATPTN	Bel600	0.5	Bel600	2	2989.85	1820.87	422	1.64	0.1013	0.05	-589.26	6568.97
TRTPN*ATPTN	Bel600	0.5	Bel600	3	3829.50	1820.87	422	2.10	0.0360	0.05	250.38	7408.61
TRTPN*ATPTN	Bel600	0.5	Bel600	4	3646.05	1820.87	422	2.00	0.0459	0.05	66.9402	7225.17
TRTPN*ATPTN	Bel600	0.5	Bel900	0	-783.77	1886.03	422	-0.42	0.6779	0.05	-4490.95	2923.41
TRTPN*ATPTN	Bel600	0.5	Bel900	0.5	-2218.44	1852.11	422	-1.20	0.2317	0.05	-5858.95	1422.07
TRTPN*ATPTN	Bel600	0.5	Bel900	1	601.03	1852.11	422	0.32	0.7457	0.05	-3039.47	4241.54
TRTPN*ATPTN	Bel600	0.5	Bel900	2	2358.79	1852.11	422	1.27	0.2035	0.05	-1281.72	5999.29
TRTPN*ATPTN	Bel600	0.5	Bel900	3	3039.05	1852.11	422	1.64	0.1016	0.05	-601.46	6679.56
TRTPN*ATPTN	Bel600	0.5	Bel900	4	4087.54	1852.11	422	2.21	0.0279	0.05	447.03	7728.05
TRTPN*ATPTN	Bel600	0.5	Oxy30	0	445.46	1925.09	422	0.23	0.8171	0.05	-3338.49	4229.41
TRTPN*ATPTN	Bel600	0.5	Oxy30	0.5	2717.61	1925.09	422	1.41	0.1588	0.05	-1066.34	6501.56
TRTPN*ATPTN	Bel600	0.5	Oxy30	1	4572.33	1886.28	422	2.42	0.0158	0.05	864.65	8280.01
TRTPN*ATPTN	Bel600	0.5	Oxy30	2	3717.18	1852.82	422	2.01	0.0455	0.05	75.2728	7359.09
TRTPN*ATPTN	Bel600	0.5	Oxy30	3	2122.34	1852.82	422	1.15	0.2527	0.05	-1519.57	5764.25
TRTPN*ATPTN	Bel600	0.5	Oxy30	4	1901.59	1852.82	422	1.03	0.3053	0.05	-1740.32	5543.50
TRTPN*ATPTN	Bel600	0.5	Oxy60	0	1905.58	1886.96	422	1.01	0.3131	0.05	-1803.44	5614.59
TRTPN*ATPTN	Bel600	0.5	Oxy60	0.5	4137.81	1886.96	422	2.19	0.0289	0.05	428.80	7846.83

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel600	0.5	Oxy60	1	6229.34	1853.41	422	3.36	0.0008	0.05	2586.28	9872.40
TRTPN*ATPTN	Bel600	0.5	Oxy60	2	7221.89	1822.19	422	3.96	<.0001	0.05	3640.19	10804
TRTPN*ATPTN	Bel600	0.5	Oxy60	3	6555.07	1822.19	422	3.60	0.0004	0.05	2973.38	10137
TRTPN*ATPTN	Bel600	0.5	Oxy60	4	6435.93	1822.19	422	3.53	0.0005	0.05	2854.24	10018
TRTPN*ATPTN	Bel600	0.5	Plac	0	2037.66	1820.82	422	1.12	0.2637	0.05	-1541.35	5616.67
TRTPN*ATPTN	Bel600	0.5	Plac	0.5	512.03	1820.82	422	0.28	0.7787	0.05	-3066.98	4091.04
TRTPN*ATPTN	Bel600	0.5	Plac	1	-439.47	1820.82	422	-0.24	0.8094	0.05	-4018.48	3139.54
TRTPN*ATPTN	Bel600	0.5	Plac	2	3626.83	1820.82	422	1.99	0.0470	0.05	47.8170	7205.84
TRTPN*ATPTN	Bel600	0.5	Plac	3	3212.76	1820.82	422	1.76	0.0784	0.05	-366.25	6791.77
TRTPN*ATPTN	Bel600	0.5	Plac	4	2033.52	1820.82	422	1.12	0.2647	0.05	-1545.49	5612.53
TRTPN*ATPTN	Bel600	1	Bel600	2	1605.23	1790.13	422	0.90	0.3704	0.05	-1913.45	5123.90
TRTPN*ATPTN	Bel600	1	Bel600	3	2444.87	1790.13	422	1.37	0.1727	0.05	-1073.81	5963.55
TRTPN*ATPTN	Bel600	1	Bel600	4	2261.43	1790.13	422	1.26	0.2072	0.05	-1257.25	5780.11
TRTPN*ATPTN	Bel600	1	Bel900	0	-2168.40	1856.55	422	-1.17	0.2435	0.05	-5817.63	1480.84
TRTPN*ATPTN	Bel600	1	Bel900	0.5	-3603.07	1822.36	422	-1.98	0.0487	0.05	-7185.09	-21.0431
TRTPN*ATPTN	Bel600	1	Bel900	1	-783.59	1822.36	422	-0.43	0.6674	0.05	-4365.62	2798.43
TRTPN*ATPTN	Bel600	1	Bel900	2	974.16	1822.36	422	0.53	0.5932	0.05	-2607.86	4556.18
TRTPN*ATPTN	Bel600	1	Bel900	3	1654.43	1822.36	422	0.91	0.3645	0.05	-1927.60	5236.45
TRTPN*ATPTN	Bel600	1	Bel900	4	2702.91	1822.36	422	1.48	0.1388	0.05	-879.11	6284.94
TRTPN*ATPTN	Bel600	1	Oxy30	0	-939.16	1896.89	422	-0.50	0.6208	0.05	-4667.68	2789.36
TRTPN*ATPTN	Bel600	1	Oxy30	0.5	1332.98	1896.89	422	0.70	0.4826	0.05	-2395.54	5061.51
TRTPN*ATPTN	Bel600	1	Oxy30	1	3187.71	1856.86	422	1.72	0.0868	0.05	-462.14	6837.55
TRTPN*ATPTN	Bel600	1	Oxy30	2	2332.55	1822.29	422	1.28	0.2012	0.05	-1249.33	5914.44
TRTPN*ATPTN	Bel600	1	Oxy30	3	737.72	1822.29	422	0.40	0.6858	0.05	-2844.17	4319.60
TRTPN*ATPTN	Bel600	1	Oxy30	4	516.96	1822.29	422	0.28	0.7768	0.05	-3064.92	4098.85

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel600	1	Oxy60	0	520.95	1857.43	422	0.28	0.7793	0.05	-3130.02	4171.93
TRTPN*ATPTN	Bel600	1	Oxy60	0.5	2753.19	1857.43	422	1.48	0.1390	0.05	-897.79	6404.16
TRTPN*ATPTN	Bel600	1	Oxy60	1	4844.71	1822.82	422	2.66	0.0082	0.05	1261.78	8427.64
TRTPN*ATPTN	Bel600	1	Oxy60	2	5837.26	1791.36	422	3.26	0.0012	0.05	2316.16	9358.37
TRTPN*ATPTN	Bel600	1	Oxy60	3	5170.45	1791.36	422	2.89	0.0041	0.05	1649.34	8691.55
TRTPN*ATPTN	Bel600	1	Oxy60	4	5051.31	1791.36	422	2.82	0.0050	0.05	1530.20	8572.41
TRTPN*ATPTN	Bel600	1	Plac	0	653.03	1790.78	422	0.36	0.7155	0.05	-2866.93	4172.99
TRTPN*ATPTN	Bel600	1	Plac	0.5	-872.60	1790.78	422	-0.49	0.6263	0.05	-4392.55	2647.36
TRTPN*ATPTN	Bel600	1	Plac	1	-1824.10	1790.78	422	-1.02	0.3090	0.05	-5344.06	1695.86
TRTPN*ATPTN	Bel600	1	Plac	2	2242.20	1790.78	422	1.25	0.2112	0.05	-1277.76	5762.16
TRTPN*ATPTN	Bel600	1	Plac	3	1828.13	1790.78	422	1.02	0.3079	0.05	-1691.83	5348.09
TRTPN*ATPTN	Bel600	1	Plac	4	648.90	1790.78	422	0.36	0.7173	0.05	-2871.06	4168.85
TRTPN*ATPTN	Bel600	2	Bel600	3	839.65	1790.13	422	0.47	0.6393	0.05	-2679.03	4358.33
TRTPN*ATPTN	Bel600	2	Bel600	4	656.20	1790.13	422	0.37	0.7141	0.05	-2862.48	4174.88
TRTPN*ATPTN	Bel600	2	Bel900	0	-3773.62	1856.55	422	-2.03	0.0427	0.05	-7422.86	-124.39
TRTPN*ATPTN	Bel600	2	Bel900	0.5	-5208.29	1822.36	422	-2.86	0.0045	0.05	-8790.32	-1626.27
TRTPN*ATPTN	Bel600	2	Bel900	1	-2388.82	1822.36	422	-1.31	0.1906	0.05	-5970.84	1193.20
TRTPN*ATPTN	Bel600	2	Bel900	2	-631.06	1822.36	422	-0.35	0.7293	0.05	-4213.09	2950.96
TRTPN*ATPTN	Bel600	2	Bel900	3	49.1998	1822.36	422	0.03	0.9785	0.05	-3532.82	3631.22
TRTPN*ATPTN	Bel600	2	Bel900	4	1097.69	1822.36	422	0.60	0.5473	0.05	-2484.33	4679.71
TRTPN*ATPTN	Bel600	2	Oxy30	0	-2544.39	1896.89	422	-1.34	0.1805	0.05	-6272.91	1184.13
TRTPN*ATPTN	Bel600	2	Oxy30	0.5	-272.24	1896.89	422	-0.14	0.8859	0.05	-4000.76	3456.28
TRTPN*ATPTN	Bel600	2	Oxy30	1	1582.48	1856.86	422	0.85	0.3946	0.05	-2067.37	5232.33
TRTPN*ATPTN	Bel600	2	Oxy30	2	727.33	1822.29	422	0.40	0.6900	0.05	-2854.56	4309.22
TRTPN*ATPTN	Bel600	2	Oxy30	3	-867.51	1822.29	422	-0.48	0.6343	0.05	-4449.40	2714.38

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel600	2	Oxy30	4	-1088.26	1822.29	422	-0.60	0.5507	0.05	-4670.15	2493.62
TRTPN*ATPTN	Bel600	2	Oxy60	0	-1084.27	1857.43	422	-0.58	0.5597	0.05	-4735.25	2566.70
TRTPN*ATPTN	Bel600	2	Oxy60	0.5	1147.96	1857.43	422	0.62	0.5369	0.05	-2503.02	4798.94
TRTPN*ATPTN	Bel600	2	Oxy60	1	3239.49	1822.82	422	1.78	0.0763	0.05	-343.45	6822.42
TRTPN*ATPTN	Bel600	2	Oxy60	2	4232.04	1791.36	422	2.36	0.0186	0.05	710.93	7753.14
TRTPN*ATPTN	Bel600	2	Oxy60	3	3565.22	1791.36	422	1.99	0.0472	0.05	44.1157	7086.33
TRTPN*ATPTN	Bel600	2	Oxy60	4	3446.08	1791.36	422	1.92	0.0551	0.05	-75.0234	6967.19
TRTPN*ATPTN	Bel600	2	Plac	0	-952.20	1790.78	422	-0.53	0.5952	0.05	-4472.15	2567.76
TRTPN*ATPTN	Bel600	2	Plac	0.5	-2477.82	1790.78	422	-1.38	0.1672	0.05	-5997.78	1042.13
TRTPN*ATPTN	Bel600	2	Plac	1	-3429.33	1790.78	422	-1.91	0.0562	0.05	-6949.28	90.6325
TRTPN*ATPTN	Bel600	2	Plac	2	636.97	1790.78	422	0.36	0.7222	0.05	-2882.98	4156.93
TRTPN*ATPTN	Bel600	2	Plac	3	222.91	1790.78	422	0.12	0.9010	0.05	-3297.05	3742.86
TRTPN*ATPTN	Bel600	2	Plac	4	-956.33	1790.78	422	-0.53	0.5936	0.05	-4476.29	2563.63
TRTPN*ATPTN	Bel600	3	Bel600	4	-183.44	1790.13	422	-0.10	0.9184	0.05	-3702.12	3335.23
TRTPN*ATPTN	Bel600	3	Bel900	0	-4613.27	1856.55	422	-2.48	0.0133	0.05	-8262.50	-964.03
TRTPN*ATPTN	Bel600	3	Bel900	0.5	-6047.94	1822.36	422	-3.32	0.0010	0.05	-9629.96	-2465.92
TRTPN*ATPTN	Bel600	3	Bel900	1	-3228.47	1822.36	422	-1.77	0.0772	0.05	-6810.49	353.56
TRTPN*ATPTN	Bel600	3	Bel900	2	-1470.71	1822.36	422	-0.81	0.4201	0.05	-5052.74	2111.31
TRTPN*ATPTN	Bel600	3	Bel900	3	-790.45	1822.36	422	-0.43	0.6647	0.05	-4372.47	2791.58
TRTPN*ATPTN	Bel600	3	Bel900	4	258.04	1822.36	422	0.14	0.8875	0.05	-3323.98	3840.07
TRTPN*ATPTN	Bel600	3	Oxy30	0	-3384.04	1896.89	422	-1.78	0.0751	0.05	-7112.56	344.48
TRTPN*ATPTN	Bel600	3	Oxy30	0.5	-1111.89	1896.89	422	-0.59	0.5581	0.05	-4840.41	2616.63
TRTPN*ATPTN	Bel600	3	Oxy30	1	742.83	1856.86	422	0.40	0.6893	0.05	-2907.01	4392.68
TRTPN*ATPTN	Bel600	3	Oxy30	2	-112.32	1822.29	422	-0.06	0.9509	0.05	-3694.20	3469.57
TRTPN*ATPTN	Bel600	3	Oxy30	3	-1707.16	1822.29	422	-0.94	0.3494	0.05	-5289.04	1874.73

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel600	3	Oxy30	4	-1927.91	1822.29	422	-1.06	0.2907	0.05	-5509.80	1653.98
TRTPN*ATPTN	Bel600	3	Oxy60	0	-1923.92	1857.43	422	-1.04	0.3009	0.05	-5574.90	1727.05
TRTPN*ATPTN	Bel600	3	Oxy60	0.5	308.31	1857.43	422	0.17	0.8682	0.05	-3342.66	3959.29
TRTPN*ATPTN	Bel600	3	Oxy60	1	2399.84	1822.82	422	1.32	0.1887	0.05	-1183.09	5982.77
TRTPN*ATPTN	Bel600	3	Oxy60	2	3392.39	1791.36	422	1.89	0.0589	0.05	-128.72	6913.49
TRTPN*ATPTN	Bel600	3	Oxy60	3	2725.57	1791.36	422	1.52	0.1289	0.05	-795.53	6246.68
TRTPN*ATPTN	Bel600	3	Oxy60	4	2606.43	1791.36	422	1.46	0.1464	0.05	-914.67	6127.54
TRTPN*ATPTN	Bel600	3	Plac	0	-1791.84	1790.78	422	-1.00	0.3176	0.05	-5311.80	1728.11
TRTPN*ATPTN	Bel600	3	Plac	0.5	-3317.47	1790.78	422	-1.85	0.0646	0.05	-6837.43	202.49
TRTPN*ATPTN	Bel600	3	Plac	1	-4268.97	1790.78	422	-2.38	0.0176	0.05	-7788.93	-749.01
TRTPN*ATPTN	Bel600	3	Plac	2	-202.67	1790.78	422	-0.11	0.9099	0.05	-3722.63	3317.29
TRTPN*ATPTN	Bel600	3	Plac	3	-616.74	1790.78	422	-0.34	0.7307	0.05	-4136.70	2903.22
TRTPN*ATPTN	Bel600	3	Plac	4	-1795.98	1790.78	422	-1.00	0.3165	0.05	-5315.93	1723.98
TRTPN*ATPTN	Bel600	4	Bel900	0	-4429.82	1856.55	422	-2.39	0.0175	0.05	-8079.06	-780.59
TRTPN*ATPTN	Bel600	4	Bel900	0.5	-5864.50	1822.36	422	-3.22	0.0014	0.05	-9446.52	-2282.47
TRTPN*ATPTN	Bel600	4	Bel900	1	-3045.02	1822.36	422	-1.67	0.0955	0.05	-6627.05	537.00
TRTPN*ATPTN	Bel600	4	Bel900	2	-1287.27	1822.36	422	-0.71	0.4803	0.05	-4869.29	2294.76
TRTPN*ATPTN	Bel600	4	Bel900	3	-607.00	1822.36	422	-0.33	0.7392	0.05	-4189.03	2975.02
TRTPN*ATPTN	Bel600	4	Bel900	4	441.49	1822.36	422	0.24	0.8087	0.05	-3140.54	4023.51
TRTPN*ATPTN	Bel600	4	Oxy30	0	-3200.59	1896.89	422	-1.69	0.0923	0.05	-6929.11	527.93
TRTPN*ATPTN	Bel600	4	Oxy30	0.5	-928.44	1896.89	422	-0.49	0.6248	0.05	-4656.96	2800.08
TRTPN*ATPTN	Bel600	4	Oxy30	1	926.28	1856.86	422	0.50	0.6182	0.05	-2723.57	4576.12
TRTPN*ATPTN	Bel600	4	Oxy30	2	71.1266	1822.29	422	0.04	0.9689	0.05	-3510.76	3653.01
TRTPN*ATPTN	Bel600	4	Oxy30	3	-1523.71	1822.29	422	-0.84	0.4035	0.05	-5105.60	2058.17
TRTPN*ATPTN	Bel600	4	Oxy30	4	-1744.46	1822.29	422	-0.96	0.3390	0.05	-5326.35	1837.42

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel600	4	Oxy60	0	-1740.48	1857.43	422	-0.94	0.3493	0.05	-5391.45	1910.50
TRTPN*ATPTN	Bel600	4	Oxy60	0.5	491.76	1857.43	422	0.26	0.7913	0.05	-3159.22	4142.73
TRTPN*ATPTN	Bel600	4	Oxy60	1	2583.28	1822.82	422	1.42	0.1572	0.05	-999.65	6166.21
TRTPN*ATPTN	Bel600	4	Oxy60	2	3575.83	1791.36	422	2.00	0.0466	0.05	54.7283	7096.94
TRTPN*ATPTN	Bel600	4	Oxy60	3	2909.02	1791.36	422	1.62	0.1051	0.05	-612.09	6430.12
TRTPN*ATPTN	Bel600	4	Oxy60	4	2789.88	1791.36	422	1.56	0.1201	0.05	-731.23	6310.98
TRTPN*ATPTN	Bel600	4	Plac	0	-1608.40	1790.78	422	-0.90	0.3696	0.05	-5128.36	1911.56
TRTPN*ATPTN	Bel600	4	Plac	0.5	-3134.03	1790.78	422	-1.75	0.0808	0.05	-6653.98	385.93
TRTPN*ATPTN	Bel600	4	Plac	1	-4085.53	1790.78	422	-2.28	0.0230	0.05	-7605.49	-565.57
TRTPN*ATPTN	Bel600	4	Plac	2	-19.2279	1790.78	422	-0.01	0.9914	0.05	-3539.19	3500.73
TRTPN*ATPTN	Bel600	4	Plac	3	-433.30	1790.78	422	-0.24	0.8089	0.05	-3953.25	3086.66
TRTPN*ATPTN	Bel600	4	Plac	4	-1612.53	1790.78	422	-0.90	0.3684	0.05	-5132.49	1907.43
TRTPN*ATPTN	Bel900	0	Bel900	0.5	-1434.67	1882.76	422	-0.76	0.4465	0.05	-5135.43	2266.09
TRTPN*ATPTN	Bel900	0	Bel900	1	1384.80	1882.76	422	0.74	0.4624	0.05	-2315.95	5085.56
TRTPN*ATPTN	Bel900	0	Bel900	2	3142.56	1882.76	422	1.67	0.0958	0.05	-558.20	6843.31
TRTPN*ATPTN	Bel900	0	Bel900	3	3822.82	1882.76	422	2.03	0.0429	0.05	122.06	7523.58
TRTPN*ATPTN	Bel900	0	Bel900	4	4871.31	1882.76	422	2.59	0.0100	0.05	1170.55	8572.07
TRTPN*ATPTN	Bel900	0	Oxy30	0	1229.23	1955.46	422	0.63	0.5299	0.05	-2614.42	5072.88
TRTPN*ATPTN	Bel900	0	Oxy30	0.5	3501.38	1955.46	422	1.79	0.0741	0.05	-342.27	7345.03
TRTPN*ATPTN	Bel900	0	Oxy30	1	5356.10	1917.18	422	2.79	0.0054	0.05	1587.70	9124.50
TRTPN*ATPTN	Bel900	0	Oxy30	2	4500.95	1884.18	422	2.39	0.0173	0.05	797.40	8204.50
TRTPN*ATPTN	Bel900	0	Oxy30	3	2906.11	1884.18	422	1.54	0.1237	0.05	-797.44	6609.66
TRTPN*ATPTN	Bel900	0	Oxy30	4	2685.36	1884.18	422	1.43	0.1548	0.05	-1018.19	6388.91
TRTPN*ATPTN	Bel900	0	Oxy60	0	2689.35	1919.01	422	1.40	0.1618	0.05	-1082.65	6461.35
TRTPN*ATPTN	Bel900	0	Oxy60	0.5	4921.58	1919.01	422	2.56	0.0107	0.05	1149.58	8693.58

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel900	0	Oxy60	1	7013.11	1886.16	422	3.72	0.0002	0.05	3305.67	10721
TRTPN*ATPTN	Bel900	0	Oxy60	2	8005.66	1855.83	422	4.31	<.0001	0.05	4357.83	11653
TRTPN*ATPTN	Bel900	0	Oxy60	3	7338.84	1855.83	422	3.95	<.0001	0.05	3691.02	10987
TRTPN*ATPTN	Bel900	0	Oxy60	4	7219.70	1855.83	422	3.89	0.0001	0.05	3571.88	10868
TRTPN*ATPTN	Bel900	0	Plac	0	2821.43	1856.35	422	1.52	0.1293	0.05	-827.42	6470.27
TRTPN*ATPTN	Bel900	0	Plac	0.5	1295.80	1856.35	422	0.70	0.4855	0.05	-2353.04	4944.64
TRTPN*ATPTN	Bel900	0	Plac	1	344.30	1856.35	422	0.19	0.8529	0.05	-3304.55	3993.14
TRTPN*ATPTN	Bel900	0	Plac	2	4410.60	1856.35	422	2.38	0.0179	0.05	761.75	8059.44
TRTPN*ATPTN	Bel900	0	Plac	3	3996.53	1856.35	422	2.15	0.0319	0.05	347.69	7645.37
TRTPN*ATPTN	Bel900	0	Plac	4	2817.29	1856.35	422	1.52	0.1299	0.05	-831.55	6466.13
TRTPN*ATPTN	Bel900	0.5	Bel900	1	2819.47	1848.84	422	1.52	0.1280	0.05	-814.60	6453.55
TRTPN*ATPTN	Bel900	0.5	Bel900	2	4577.23	1848.84	422	2.48	0.0137	0.05	943.15	8211.30
TRTPN*ATPTN	Bel900	0.5	Bel900	3	5257.49	1848.84	422	2.84	0.0047	0.05	1623.42	8891.57
TRTPN*ATPTN	Bel900	0.5	Bel900	4	6305.98	1848.84	422	3.41	0.0007	0.05	2671.91	9940.06
TRTPN*ATPTN	Bel900	0.5	Oxy30	0	2663.90	1922.09	422	1.39	0.1665	0.05	-1114.16	6441.96
TRTPN*ATPTN	Bel900	0.5	Oxy30	0.5	4936.05	1922.09	422	2.57	0.0106	0.05	1157.99	8714.11
TRTPN*ATPTN	Bel900	0.5	Oxy30	1	6790.77	1883.48	422	3.61	0.0003	0.05	3088.59	10493
TRTPN*ATPTN	Bel900	0.5	Oxy30	2	5935.62	1850.21	422	3.21	0.0014	0.05	2298.84	9572.40
TRTPN*ATPTN	Bel900	0.5	Oxy30	3	4340.78	1850.21	422	2.35	0.0194	0.05	704.00	7977.56
TRTPN*ATPTN	Bel900	0.5	Oxy30	4	4120.03	1850.21	422	2.23	0.0265	0.05	483.25	7756.81
TRTPN*ATPTN	Bel900	0.5	Oxy60	0	4124.02	1886.21	422	2.19	0.0293	0.05	416.48	7831.56
TRTPN*ATPTN	Bel900	0.5	Oxy60	0.5	6356.25	1886.21	422	3.37	0.0008	0.05	2648.71	10064
TRTPN*ATPTN	Bel900	0.5	Oxy60	1	8447.78	1853.71	422	4.56	<.0001	0.05	4804.11	12091
TRTPN*ATPTN	Bel900	0.5	Oxy60	2	9440.33	1822.31	422	5.18	<.0001	0.05	5858.39	13022
TRTPN*ATPTN	Bel900	0.5	Oxy60	3	8773.51	1822.31	422	4.81	<.0001	0.05	5191.57	12355

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel900	0.5	Oxy60	4	8654.37	1822.31	422	4.75	<.0001	0.05	5072.43	12236
TRTPN*ATPTN	Bel900	0.5	Plac	0	4256.10	1822.11	422	2.34	0.0200	0.05	674.55	7837.64
TRTPN*ATPTN	Bel900	0.5	Plac	0.5	2730.47	1822.11	422	1.50	0.1347	0.05	-851.07	6312.01
TRTPN*ATPTN	Bel900	0.5	Plac	1	1778.97	1822.11	422	0.98	0.3295	0.05	-1802.58	5360.51
TRTPN*ATPTN	Bel900	0.5	Plac	2	5845.27	1822.11	422	3.21	0.0014	0.05	2263.72	9426.81
TRTPN*ATPTN	Bel900	0.5	Plac	3	5431.20	1822.11	422	2.98	0.0030	0.05	1849.65	9012.74
TRTPN*ATPTN	Bel900	0.5	Plac	4	4251.96	1822.11	422	2.33	0.0201	0.05	670.42	7833.51
TRTPN*ATPTN	Bel900	1	Bel900	2	1757.75	1848.84	422	0.95	0.3423	0.05	-1876.32	5391.83
TRTPN*ATPTN	Bel900	1	Bel900	3	2438.02	1848.84	422	1.32	0.1880	0.05	-1196.06	6072.09
TRTPN*ATPTN	Bel900	1	Bel900	4	3486.51	1848.84	422	1.89	0.0600	0.05	-147.57	7120.58
TRTPN*ATPTN	Bel900	1	Oxy30	0	-155.57	1922.09	422	-0.08	0.9355	0.05	-3933.63	3622.49
TRTPN*ATPTN	Bel900	1	Oxy30	0.5	2116.58	1922.09	422	1.10	0.2714	0.05	-1661.48	5894.64
TRTPN*ATPTN	Bel900	1	Oxy30	1	3971.30	1883.48	422	2.11	0.0356	0.05	269.12	7673.48
TRTPN*ATPTN	Bel900	1	Oxy30	2	3116.15	1850.21	422	1.68	0.0929	0.05	-520.63	6752.93
TRTPN*ATPTN	Bel900	1	Oxy30	3	1521.31	1850.21	422	0.82	0.4114	0.05	-2115.47	5158.09
TRTPN*ATPTN	Bel900	1	Oxy30	4	1300.56	1850.21	422	0.70	0.4825	0.05	-2336.22	4937.34
TRTPN*ATPTN	Bel900	1	Oxy60	0	1304.54	1886.21	422	0.69	0.4896	0.05	-2403.00	5012.08
TRTPN*ATPTN	Bel900	1	Oxy60	0.5	3536.78	1886.21	422	1.88	0.0615	0.05	-170.76	7244.32
TRTPN*ATPTN	Bel900	1	Oxy60	1	5628.30	1853.71	422	3.04	0.0025	0.05	1984.64	9271.97
TRTPN*ATPTN	Bel900	1	Oxy60	2	6620.86	1822.31	422	3.63	0.0003	0.05	3038.91	10203
TRTPN*ATPTN	Bel900	1	Oxy60	3	5954.04	1822.31	422	3.27	0.0012	0.05	2372.10	9535.98
TRTPN*ATPTN	Bel900	1	Oxy60	4	5834.90	1822.31	422	3.20	0.0015	0.05	2252.96	9416.84
TRTPN*ATPTN	Bel900	1	Plac	0	1436.62	1822.11	422	0.79	0.4309	0.05	-2144.92	5018.17
TRTPN*ATPTN	Bel900	1	Plac	0.5	-89.0037	1822.11	422	-0.05	0.9611	0.05	-3670.55	3492.54
TRTPN*ATPTN	Bel900	1	Plac	1	-1040.51	1822.11	422	-0.57	0.5683	0.05	-4622.05	2541.04

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel900	1	Plac	2	3025.79	1822.11	422	1.66	0.0975	0.05	-555.75	6607.34
TRTPN*ATPTN	Bel900	1	Plac	3	2611.72	1822.11	422	1.43	0.1525	0.05	-969.82	6193.27
TRTPN*ATPTN	Bel900	1	Plac	4	1432.49	1822.11	422	0.79	0.4322	0.05	-2149.05	5014.03
TRTPN*ATPTN	Bel900	2	Bel900	3	680.26	1848.84	422	0.37	0.7131	0.05	-2953.81	4314.34
TRTPN*ATPTN	Bel900	2	Bel900	4	1728.75	1848.84	422	0.94	0.3503	0.05	-1905.32	5362.83
TRTPN*ATPTN	Bel900	2	Oxy30	0	-1913.32	1922.09	422	-1.00	0.3201	0.05	-5691.38	1864.73
TRTPN*ATPTN	Bel900	2	Oxy30	0.5	358.82	1922.09	422	0.19	0.8520	0.05	-3419.24	4136.88
TRTPN*ATPTN	Bel900	2	Oxy30	1	2213.54	1883.48	422	1.18	0.2406	0.05	-1488.64	5915.72
TRTPN*ATPTN	Bel900	2	Oxy30	2	1358.39	1850.21	422	0.73	0.4632	0.05	-2278.39	4995.17
TRTPN*ATPTN	Bel900	2	Oxy30	3	-236.44	1850.21	422	-0.13	0.8984	0.05	-3873.23	3400.34
TRTPN*ATPTN	Bel900	2	Oxy30	4	-457.20	1850.21	422	-0.25	0.8049	0.05	-4093.98	3179.58
TRTPN*ATPTN	Bel900	2	Oxy60	0	-453.21	1886.21	422	-0.24	0.8102	0.05	-4160.75	3254.33
TRTPN*ATPTN	Bel900	2	Oxy60	0.5	1779.02	1886.21	422	0.94	0.3461	0.05	-1928.51	5486.56
TRTPN*ATPTN	Bel900	2	Oxy60	1	3870.55	1853.71	422	2.09	0.0374	0.05	226.89	7514.21
TRTPN*ATPTN	Bel900	2	Oxy60	2	4863.10	1822.31	422	2.67	0.0079	0.05	1281.16	8445.04
TRTPN*ATPTN	Bel900	2	Oxy60	3	4196.29	1822.31	422	2.30	0.0218	0.05	614.34	7778.23
TRTPN*ATPTN	Bel900	2	Oxy60	4	4077.15	1822.31	422	2.24	0.0258	0.05	495.20	7659.09
TRTPN*ATPTN	Bel900	2	Plac	0	-321.13	1822.11	422	-0.18	0.8602	0.05	-3902.68	3260.41
TRTPN*ATPTN	Bel900	2	Plac	0.5	-1846.76	1822.11	422	-1.01	0.3114	0.05	-5428.30	1734.79
TRTPN*ATPTN	Bel900	2	Plac	1	-2798.26	1822.11	422	-1.54	0.1254	0.05	-6379.80	783.28
TRTPN*ATPTN	Bel900	2	Plac	2	1268.04	1822.11	422	0.70	0.4869	0.05	-2313.50	4849.58
TRTPN*ATPTN	Bel900	2	Plac	3	853.97	1822.11	422	0.47	0.6395	0.05	-2727.57	4435.51
TRTPN*ATPTN	Bel900	2	Plac	4	-325.26	1822.11	422	-0.18	0.8584	0.05	-3906.81	3256.28
TRTPN*ATPTN	Bel900	3	Bel900	4	1048.49	1848.84	422	0.57	0.5709	0.05	-2585.59	4682.56
TRTPN*ATPTN	Bel900	3	Oxy30	0	-2593.59	1922.09	422	-1.35	0.1779	0.05	-6371.65	1184.47

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel900	3	Oxy30	0.5	-321.44	1922.09	422	-0.17	0.8673	0.05	-4099.50	3456.62
TRTPN*ATPTN	Bel900	3	Oxy30	1	1533.28	1883.48	422	0.81	0.4161	0.05	-2168.90	5235.46
TRTPN*ATPTN	Bel900	3	Oxy30	2	678.13	1850.21	422	0.37	0.7142	0.05	-2958.65	4314.91
TRTPN*ATPTN	Bel900	3	Oxy30	3	-916.71	1850.21	422	-0.50	0.6205	0.05	-4553.49	2720.07
TRTPN*ATPTN	Bel900	3	Oxy30	4	-1137.46	1850.21	422	-0.61	0.5390	0.05	-4774.24	2499.32
TRTPN*ATPTN	Bel900	3	Oxy60	0	-1133.47	1886.21	422	-0.60	0.5482	0.05	-4841.01	2574.06
TRTPN*ATPTN	Bel900	3	Oxy60	0.5	1098.76	1886.21	422	0.58	0.5605	0.05	-2608.78	4806.30
TRTPN*ATPTN	Bel900	3	Oxy60	1	3190.29	1853.71	422	1.72	0.0860	0.05	-453.38	6833.95
TRTPN*ATPTN	Bel900	3	Oxy60	2	4182.84	1822.31	422	2.30	0.0222	0.05	600.89	7764.78
TRTPN*ATPTN	Bel900	3	Oxy60	3	3516.02	1822.31	422	1.93	0.0543	0.05	-65.9217	7097.96
TRTPN*ATPTN	Bel900	3	Oxy60	4	3396.88	1822.31	422	1.86	0.0630	0.05	-185.06	6978.83
TRTPN*ATPTN	Bel900	3	Plac	0	-1001.40	1822.11	422	-0.55	0.5829	0.05	-4582.94	2580.15
TRTPN*ATPTN	Bel900	3	Plac	0.5	-2527.02	1822.11	422	-1.39	0.1662	0.05	-6108.57	1054.52
TRTPN*ATPTN	Bel900	3	Plac	1	-3478.52	1822.11	422	-1.91	0.0569	0.05	-7060.07	103.02
TRTPN*ATPTN	Bel900	3	Plac	2	587.78	1822.11	422	0.32	0.7472	0.05	-2993.77	4169.32
TRTPN*ATPTN	Bel900	3	Plac	3	173.71	1822.11	422	0.10	0.9241	0.05	-3407.84	3755.25
TRTPN*ATPTN	Bel900	3	Plac	4	-1005.53	1822.11	422	-0.55	0.5813	0.05	-4587.07	2576.02
TRTPN*ATPTN	Bel900	4	Oxy30	0	-3642.08	1922.09	422	-1.89	0.0588	0.05	-7420.14	135.98
TRTPN*ATPTN	Bel900	4	Oxy30	0.5	-1369.93	1922.09	422	-0.71	0.4764	0.05	-5147.99	2408.13
TRTPN*ATPTN	Bel900	4	Oxy30	1	484.79	1883.48	422	0.26	0.7970	0.05	-3217.39	4186.97
TRTPN*ATPTN	Bel900	4	Oxy30	2	-370.36	1850.21	422	-0.20	0.8414	0.05	-4007.14	3266.42
TRTPN*ATPTN	Bel900	4	Oxy30	3	-1965.20	1850.21	422	-1.06	0.2888	0.05	-5601.98	1671.58
TRTPN*ATPTN	Bel900	4	Oxy30	4	-2185.95	1850.21	422	-1.18	0.2381	0.05	-5822.73	1450.83
TRTPN*ATPTN	Bel900	4	Oxy60	0	-2181.96	1886.21	422	-1.16	0.2480	0.05	-5889.50	1525.58
TRTPN*ATPTN	Bel900	4	Oxy60	0.5	50.2714	1886.21	422	0.03	0.9787	0.05	-3657.27	3757.81

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Bel900	4	Oxy60	1	2141.80	1853.71	422	1.16	0.2486	0.05	-1501.87	5785.46
TRTPN*ATPTN	Bel900	4	Oxy60	2	3134.35	1822.31	422	1.72	0.0862	0.05	-447.60	6716.29
TRTPN*ATPTN	Bel900	4	Oxy60	3	2467.53	1822.31	422	1.35	0.1764	0.05	-1114.41	6049.48
TRTPN*ATPTN	Bel900	4	Oxy60	4	2348.39	1822.31	422	1.29	0.1982	0.05	-1233.55	5930.34
TRTPN*ATPTN	Bel900	4	Plac	0	-2049.89	1822.11	422	-1.13	0.2612	0.05	-5631.43	1531.66
TRTPN*ATPTN	Bel900	4	Plac	0.5	-3575.51	1822.11	422	-1.96	0.0504	0.05	-7157.06	6.0322
TRTPN*ATPTN	Bel900	4	Plac	1	-4527.01	1822.11	422	-2.48	0.0134	0.05	-8108.56	-945.47
TRTPN*ATPTN	Bel900	4	Plac	2	-460.71	1822.11	422	-0.25	0.8005	0.05	-4042.26	3120.83
TRTPN*ATPTN	Bel900	4	Plac	3	-874.78	1822.11	422	-0.48	0.6314	0.05	-4456.33	2706.76
TRTPN*ATPTN	Bel900	4	Plac	4	-2054.02	1822.11	422	-1.13	0.2603	0.05	-5635.56	1527.53
TRTPN*ATPTN	Oxy30	0	Oxy30	0.5	2272.15	1985.97	422	1.14	0.2532	0.05	-1631.47	6175.77
TRTPN*ATPTN	Oxy30	0	Oxy30	1	4126.87	1951.67	422	2.11	0.0351	0.05	290.66	7963.08
TRTPN*ATPTN	Oxy30	0	Oxy30	2	3271.72	1922.33	422	1.70	0.0895	0.05	-506.82	7050.26
TRTPN*ATPTN	Oxy30	0	Oxy30	3	1676.88	1922.33	422	0.87	0.3835	0.05	-2101.66	5455.42
TRTPN*ATPTN	Oxy30	0	Oxy30	4	1456.13	1922.33	422	0.76	0.4492	0.05	-2322.41	5234.66
TRTPN*ATPTN	Oxy30	0	Oxy60	0	1460.11	1958.61	422	0.75	0.4564	0.05	-2389.73	5309.95
TRTPN*ATPTN	Oxy30	0	Oxy60	0.5	3692.35	1958.61	422	1.89	0.0601	0.05	-157.49	7542.19
TRTPN*ATPTN	Oxy30	0	Oxy60	1	5783.87	1927.80	422	3.00	0.0029	0.05	1994.59	9573.16
TRTPN*ATPTN	Oxy30	0	Oxy60	2	6776.43	1896.92	422	3.57	0.0004	0.05	3047.84	10505
TRTPN*ATPTN	Oxy30	0	Oxy60	3	6109.61	1896.92	422	3.22	0.0014	0.05	2381.03	9838.19
TRTPN*ATPTN	Oxy30	0	Oxy60	4	5990.47	1896.92	422	3.16	0.0017	0.05	2261.89	9719.05
TRTPN*ATPTN	Oxy30	0	Plac	0	1592.19	1895.07	422	0.84	0.4013	0.05	-2132.76	5317.15
TRTPN*ATPTN	Oxy30	0	Plac	0.5	66.5664	1895.07	422	0.04	0.9720	0.05	-3658.39	3791.52
TRTPN*ATPTN	Oxy30	0	Plac	1	-884.94	1895.07	422	-0.47	0.6408	0.05	-4609.89	2840.02
TRTPN*ATPTN	Oxy30	0	Plac	2	3181.36	1895.07	422	1.68	0.0939	0.05	-543.59	6906.32

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Oxy30	0	Plac	3	2767.29	1895.07	422	1.46	0.1450	0.05	-957.66	6492.25
TRTPN*ATPTN	Oxy30	0	Plac	4	1588.06	1895.07	422	0.84	0.4025	0.05	-2136.89	5313.01
TRTPN*ATPTN	Oxy30	0.5	Oxy30	1	1854.72	1951.67	422	0.95	0.3425	0.05	-1981.49	5690.93
TRTPN*ATPTN	Oxy30	0.5	Oxy30	2	999.57	1922.33	422	0.52	0.6034	0.05	-2778.97	4778.11
TRTPN*ATPTN	Oxy30	0.5	Oxy30	3	-595.27	1922.33	422	-0.31	0.7570	0.05	-4373.81	3183.27
TRTPN*ATPTN	Oxy30	0.5	Oxy30	4	-816.02	1922.33	422	-0.42	0.6714	0.05	-4594.56	2962.52
TRTPN*ATPTN	Oxy30	0.5	Oxy60	0	-812.03	1958.61	422	-0.41	0.6786	0.05	-4661.87	3037.81
TRTPN*ATPTN	Oxy30	0.5	Oxy60	0.5	1420.20	1958.61	422	0.73	0.4688	0.05	-2429.64	5270.04
TRTPN*ATPTN	Oxy30	0.5	Oxy60	1	3511.73	1927.80	422	1.82	0.0692	0.05	-277.56	7301.02
TRTPN*ATPTN	Oxy30	0.5	Oxy60	2	4504.28	1896.92	422	2.37	0.0180	0.05	775.69	8232.86
TRTPN*ATPTN	Oxy30	0.5	Oxy60	3	3837.46	1896.92	422	2.02	0.0437	0.05	108.88	7566.04
TRTPN*ATPTN	Oxy30	0.5	Oxy60	4	3718.32	1896.92	422	1.96	0.0506	0.05	-10.2601	7446.91
TRTPN*ATPTN	Oxy30	0.5	Plac	0	-679.96	1895.07	422	-0.36	0.7199	0.05	-4404.91	3045.00
TRTPN*ATPTN	Oxy30	0.5	Plac	0.5	-2205.58	1895.07	422	-1.16	0.2451	0.05	-5930.54	1519.37
TRTPN*ATPTN	Oxy30	0.5	Plac	1	-3157.08	1895.07	422	-1.67	0.0965	0.05	-6882.04	567.87
TRTPN*ATPTN	Oxy30	0.5	Plac	2	909.22	1895.07	422	0.48	0.6316	0.05	-2815.74	4634.17
TRTPN*ATPTN	Oxy30	0.5	Plac	3	495.15	1895.07	422	0.26	0.7940	0.05	-3229.81	4220.10
TRTPN*ATPTN	Oxy30	0.5	Plac	4	-684.09	1895.07	422	-0.36	0.7183	0.05	-4409.04	3040.87
TRTPN*ATPTN	Oxy30	1	Oxy30	2	-855.15	1882.89	422	-0.45	0.6499	0.05	-4556.16	2845.86
TRTPN*ATPTN	Oxy30	1	Oxy30	3	-2449.99	1882.89	422	-1.30	0.1939	0.05	-6150.99	1251.02
TRTPN*ATPTN	Oxy30	1	Oxy30	4	-2670.74	1882.89	422	-1.42	0.1568	0.05	-6371.75	1030.26
TRTPN*ATPTN	Oxy30	1	Oxy60	0	-2666.75	1920.15	422	-1.39	0.1656	0.05	-6441.00	1107.49
TRTPN*ATPTN	Oxy30	1	Oxy60	0.5	-434.52	1920.15	422	-0.23	0.8211	0.05	-4208.76	3339.72
TRTPN*ATPTN	Oxy30	1	Oxy60	1	1657.01	1888.02	422	0.88	0.3806	0.05	-2054.09	5368.10
TRTPN*ATPTN	Oxy30	1	Oxy60	2	2649.56	1856.88	422	1.43	0.1544	0.05	-1000.32	6299.43

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Oxy30	1	Oxy60	3	1982.74	1856.88	422	1.07	0.2862	0.05	-1667.14	5632.62
TRTPN*ATPTN	Oxy30	1	Oxy60	4	1863.60	1856.88	422	1.00	0.3161	0.05	-1786.27	5513.48
TRTPN*ATPTN	Oxy30	1	Plac	0	-2534.68	1855.92	422	-1.37	0.1728	0.05	-6182.68	1113.32
TRTPN*ATPTN	Oxy30	1	Plac	0.5	-4060.30	1855.92	422	-2.19	0.0292	0.05	-7708.30	-412.30
TRTPN*ATPTN	Oxy30	1	Plac	1	-5011.80	1855.92	422	-2.70	0.0072	0.05	-8659.81	-1363.80
TRTPN*ATPTN	Oxy30	1	Plac	2	-945.50	1855.92	422	-0.51	0.6107	0.05	-4593.51	2702.50
TRTPN*ATPTN	Oxy30	1	Plac	3	-1359.57	1855.92	422	-0.73	0.4642	0.05	-5007.57	2288.43
TRTPN*ATPTN	Oxy30	1	Plac	4	-2538.81	1855.92	422	-1.37	0.1721	0.05	-6186.81	1109.19
TRTPN*ATPTN	Oxy30	2	Oxy30	3	-1594.84	1848.84	422	-0.86	0.3888	0.05	-5228.91	2039.24
TRTPN*ATPTN	Oxy30	2	Oxy30	4	-1815.59	1848.84	422	-0.98	0.3267	0.05	-5449.67	1818.48
TRTPN*ATPTN	Oxy30	2	Oxy60	0	-1811.60	1886.98	422	-0.96	0.3376	0.05	-5520.66	1897.45
TRTPN*ATPTN	Oxy30	2	Oxy60	0.5	420.63	1886.98	422	0.22	0.8237	0.05	-3288.43	4129.69
TRTPN*ATPTN	Oxy30	2	Oxy60	1	2512.16	1853.66	422	1.36	0.1761	0.05	-1131.39	6155.71
TRTPN*ATPTN	Oxy30	2	Oxy60	2	3504.71	1822.29	422	1.92	0.0551	0.05	-77.1821	7086.60
TRTPN*ATPTN	Oxy30	2	Oxy60	3	2837.89	1822.29	422	1.56	0.1201	0.05	-744.00	6419.78
TRTPN*ATPTN	Oxy30	2	Oxy60	4	2718.75	1822.29	422	1.49	0.1365	0.05	-863.14	6300.64
TRTPN*ATPTN	Oxy30	2	Plac	0	-1679.53	1822.16	422	-0.92	0.3572	0.05	-5261.16	1902.11
TRTPN*ATPTN	Oxy30	2	Plac	0.5	-3205.15	1822.16	422	-1.76	0.0793	0.05	-6786.79	376.49
TRTPN*ATPTN	Oxy30	2	Plac	1	-4156.65	1822.16	422	-2.28	0.0230	0.05	-7738.29	-575.02
TRTPN*ATPTN	Oxy30	2	Plac	2	-90.3546	1822.16	422	-0.05	0.9605	0.05	-3671.99	3491.28
TRTPN*ATPTN	Oxy30	2	Plac	3	-504.42	1822.16	422	-0.28	0.7820	0.05	-4086.06	3077.21
TRTPN*ATPTN	Oxy30	2	Plac	4	-1683.66	1822.16	422	-0.92	0.3560	0.05	-5265.30	1897.98
TRTPN*ATPTN	Oxy30	3	Oxy30	4	-220.75	1848.84	422	-0.12	0.9050	0.05	-3854.83	3413.32
TRTPN*ATPTN	Oxy30	3	Oxy60	0	-216.77	1886.98	422	-0.11	0.9086	0.05	-3925.82	3492.29
TRTPN*ATPTN	Oxy30	3	Oxy60	0.5	2015.47	1886.98	422	1.07	0.2861	0.05	-1693.59	5724.53

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Oxy30	3	Oxy60	1	4106.99	1853.66	422	2.22	0.0273	0.05	463.44	7750.55
TRTPN*ATPTN	Oxy30	3	Oxy60	2	5099.55	1822.29	422	2.80	0.0054	0.05	1517.66	8681.43
TRTPN*ATPTN	Oxy30	3	Oxy60	3	4432.73	1822.29	422	2.43	0.0154	0.05	850.84	8014.62
TRTPN*ATPTN	Oxy30	3	Oxy60	4	4313.59	1822.29	422	2.37	0.0184	0.05	731.70	7895.48
TRTPN*ATPTN	Oxy30	3	Plac	0	-84.6873	1822.16	422	-0.05	0.9630	0.05	-3666.33	3496.95
TRTPN*ATPTN	Oxy30	3	Plac	0.5	-1610.31	1822.16	422	-0.88	0.3773	0.05	-5191.95	1971.32
TRTPN*ATPTN	Oxy30	3	Plac	1	-2561.82	1822.16	422	-1.41	0.1605	0.05	-6143.45	1019.82
TRTPN*ATPTN	Oxy30	3	Plac	2	1504.48	1822.16	422	0.83	0.4095	0.05	-2077.15	5086.12
TRTPN*ATPTN	Oxy30	3	Plac	3	1090.41	1822.16	422	0.60	0.5499	0.05	-2491.22	4672.05
TRTPN*ATPTN	Oxy30	3	Plac	4	-88.8197	1822.16	422	-0.05	0.9611	0.05	-3670.46	3492.82
TRTPN*ATPTN	Oxy30	4	Oxy60	0	3.9867	1886.98	422	0.00	0.9983	0.05	-3705.07	3713.04
TRTPN*ATPTN	Oxy30	4	Oxy60	0.5	2236.22	1886.98	422	1.19	0.2367	0.05	-1472.83	5945.28
TRTPN*ATPTN	Oxy30	4	Oxy60	1	4327.75	1853.66	422	2.33	0.0200	0.05	684.20	7971.30
TRTPN*ATPTN	Oxy30	4	Oxy60	2	5320.30	1822.29	422	2.92	0.0037	0.05	1738.41	8902.19
TRTPN*ATPTN	Oxy30	4	Oxy60	3	4653.48	1822.29	422	2.55	0.0110	0.05	1071.59	8235.37
TRTPN*ATPTN	Oxy30	4	Oxy60	4	4534.34	1822.29	422	2.49	0.0132	0.05	952.45	8116.23
TRTPN*ATPTN	Oxy30	4	Plac	0	136.07	1822.16	422	0.07	0.9405	0.05	-3445.57	3717.70
TRTPN*ATPTN	Oxy30	4	Plac	0.5	-1389.56	1822.16	422	-0.76	0.4461	0.05	-4971.20	2192.08
TRTPN*ATPTN	Oxy30	4	Plac	1	-2341.06	1822.16	422	-1.28	0.1996	0.05	-5922.70	1240.57
TRTPN*ATPTN	Oxy30	4	Plac	2	1725.24	1822.16	422	0.95	0.3443	0.05	-1856.40	5306.87
TRTPN*ATPTN	Oxy30	4	Plac	3	1311.17	1822.16	422	0.72	0.4722	0.05	-2270.47	4892.81
TRTPN*ATPTN	Oxy30	4	Plac	4	131.93	1822.16	422	0.07	0.9423	0.05	-3449.71	3713.57
TRTPN*ATPTN	Oxy60	0	Oxy60	0.5	2232.24	1913.73	422	1.17	0.2441	0.05	-1529.39	5993.86
TRTPN*ATPTN	Oxy60	0	Oxy60	1	4323.76	1885.44	422	2.29	0.0223	0.05	617.73	8029.79
TRTPN*ATPTN	Oxy60	0	Oxy60	2	5316.31	1855.33	422	2.87	0.0044	0.05	1669.47	8963.15

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Oxy60	0	Oxy60	3	4649.50	1855.33	422	2.51	0.0126	0.05	1002.66	8296.33
TRTPN*ATPTN	Oxy60	0	Oxy60	4	4530.36	1855.33	422	2.44	0.0150	0.05	883.52	8177.20
TRTPN*ATPTN	Oxy60	0	Plac	0	132.08	1856.77	422	0.07	0.9433	0.05	-3517.59	3781.75
TRTPN*ATPTN	Oxy60	0	Plac	0.5	-1393.55	1856.77	422	-0.75	0.4534	0.05	-5043.22	2256.12
TRTPN*ATPTN	Oxy60	0	Plac	1	-2345.05	1856.77	422	-1.26	0.2073	0.05	-5994.72	1304.62
TRTPN*ATPTN	Oxy60	0	Plac	2	1721.25	1856.77	422	0.93	0.3544	0.05	-1928.42	5370.92
TRTPN*ATPTN	Oxy60	0	Plac	3	1307.18	1856.77	422	0.70	0.4818	0.05	-2342.49	4956.85
TRTPN*ATPTN	Oxy60	0	Plac	4	127.95	1856.77	422	0.07	0.9451	0.05	-3521.72	3777.62
TRTPN*ATPTN	Oxy60	0.5	Oxy60	1	2091.53	1885.44	422	1.11	0.2679	0.05	-1614.50	5797.55
TRTPN*ATPTN	Oxy60	0.5	Oxy60	2	3084.08	1855.33	422	1.66	0.0972	0.05	-562.76	6730.91
TRTPN*ATPTN	Oxy60	0.5	Oxy60	3	2417.26	1855.33	422	1.30	0.1933	0.05	-1229.58	6064.10
TRTPN*ATPTN	Oxy60	0.5	Oxy60	4	2298.12	1855.33	422	1.24	0.2162	0.05	-1348.72	5944.96
TRTPN*ATPTN	Oxy60	0.5	Plac	0	-2100.16	1856.77	422	-1.13	0.2587	0.05	-5749.83	1549.51
TRTPN*ATPTN	Oxy60	0.5	Plac	0.5	-3625.78	1856.77	422	-1.95	0.0515	0.05	-7275.45	23.8874
TRTPN*ATPTN	Oxy60	0.5	Plac	1	-4577.29	1856.77	422	-2.47	0.0141	0.05	-8226.96	-927.62
TRTPN*ATPTN	Oxy60	0.5	Plac	2	-510.99	1856.77	422	-0.28	0.7833	0.05	-4160.66	3138.68
TRTPN*ATPTN	Oxy60	0.5	Plac	3	-925.05	1856.77	422	-0.50	0.6186	0.05	-4574.72	2724.62
TRTPN*ATPTN	Oxy60	0.5	Plac	4	-2104.29	1856.77	422	-1.13	0.2577	0.05	-5753.96	1545.38
TRTPN*ATPTN	Oxy60	1	Oxy60	2	992.55	1820.88	422	0.55	0.5860	0.05	-2586.57	4571.67
TRTPN*ATPTN	Oxy60	1	Oxy60	3	325.74	1820.88	422	0.18	0.8581	0.05	-3253.39	3904.86
TRTPN*ATPTN	Oxy60	1	Oxy60	4	206.60	1820.88	422	0.11	0.9097	0.05	-3372.52	3785.72
TRTPN*ATPTN	Oxy60	1	Plac	0	-4191.68	1822.94	422	-2.30	0.0220	0.05	-7774.85	-608.51
TRTPN*ATPTN	Oxy60	1	Plac	0.5	-5717.31	1822.94	422	-3.14	0.0018	0.05	-9300.48	-2134.14
TRTPN*ATPTN	Oxy60	1	Plac	1	-6668.81	1822.94	422	-3.66	0.0003	0.05	-10252	-3085.64
TRTPN*ATPTN	Oxy60	1	Plac	2	-2602.51	1822.94	422	-1.43	0.1541	0.05	-6185.68	980.66

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Oxy60	1	Plac	3	-3016.58	1822.94	422	-1.65	0.0987	0.05	-6599.75	566.59
TRTPN*ATPTN	Oxy60	1	Plac	4	-4195.81	1822.94	422	-2.30	0.0218	0.05	-7778.98	-612.64
TRTPN*ATPTN	Oxy60	2	Oxy60	3	-666.82	1790.13	422	-0.37	0.7097	0.05	-4185.49	2851.86
TRTPN*ATPTN	Oxy60	2	Oxy60	4	-785.95	1790.13	422	-0.44	0.6609	0.05	-4304.63	2732.72
TRTPN*ATPTN	Oxy60	2	Plac	0	-5184.23	1791.43	422	-2.89	0.0040	0.05	-8705.46	-1663.00
TRTPN*ATPTN	Oxy60	2	Plac	0.5	-6709.86	1791.43	422	-3.75	0.0002	0.05	-10231	-3188.63
TRTPN*ATPTN	Oxy60	2	Plac	1	-7661.36	1791.43	422	-4.28	<.0001	0.05	-11183	-4140.13
TRTPN*ATPTN	Oxy60	2	Plac	2	-3595.06	1791.43	422	-2.01	0.0454	0.05	-7116.29	-73.8314
TRTPN*ATPTN	Oxy60	2	Plac	3	-4009.13	1791.43	422	-2.24	0.0257	0.05	-7530.36	-487.90
TRTPN*ATPTN	Oxy60	2	Plac	4	-5188.37	1791.43	422	-2.90	0.0040	0.05	-8709.60	-1667.13
TRTPN*ATPTN	Oxy60	3	Oxy60	4	-119.14	1790.13	422	-0.07	0.9470	0.05	-3637.82	3399.54
TRTPN*ATPTN	Oxy60	3	Plac	0	-4517.42	1791.43	422	-2.52	0.0120	0.05	-8038.65	-996.19
TRTPN*ATPTN	Oxy60	3	Plac	0.5	-6043.04	1791.43	422	-3.37	0.0008	0.05	-9564.27	-2521.81
TRTPN*ATPTN	Oxy60	3	Plac	1	-6994.55	1791.43	422	-3.90	0.0001	0.05	-10516	-3473.32
TRTPN*ATPTN	Oxy60	3	Plac	2	-2928.25	1791.43	422	-1.63	0.1029	0.05	-6449.48	592.98
TRTPN*ATPTN	Oxy60	3	Plac	3	-3342.32	1791.43	422	-1.87	0.0628	0.05	-6863.55	178.91
TRTPN*ATPTN	Oxy60	3	Plac	4	-4521.55	1791.43	422	-2.52	0.0120	0.05	-8042.78	-1000.32
TRTPN*ATPTN	Oxy60	4	Plac	0	-4398.28	1791.43	422	-2.46	0.0145	0.05	-7919.51	-877.05
TRTPN*ATPTN	Oxy60	4	Plac	0.5	-5923.90	1791.43	422	-3.31	0.0010	0.05	-9445.13	-2402.67
TRTPN*ATPTN	Oxy60	4	Plac	1	-6875.41	1791.43	422	-3.84	0.0001	0.05	-10397	-3354.18
TRTPN*ATPTN	Oxy60	4	Plac	2	-2809.11	1791.43	422	-1.57	0.1176	0.05	-6330.34	712.12
TRTPN*ATPTN	Oxy60	4	Plac	3	-3223.18	1791.43	422	-1.80	0.0727	0.05	-6744.41	298.05
TRTPN*ATPTN	Oxy60	4	Plac	4	-4402.41	1791.43	422	-2.46	0.0144	0.05	-7923.64	-881.18
TRTPN*ATPTN	Plac	0	Plac	0.5	-1525.63	1790.13	422	-0.85	0.3946	0.05	-5044.30	1993.05
TRTPN*ATPTN	Plac	0	Plac	1	-2477.13	1790.13	422	-1.38	0.1672	0.05	-5995.81	1041.55

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM

Differences of Least Squares Means

Effect	Planned Treatment (N)	Analysis Timepoint (N)	Planned Treatment (N)	Analysis Timepoint (N)	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTPN*ATPTN	Plac	0	Plac	2	1589.17	1790.13	422	0.89	0.3752	0.05	-1929.51	5107.85
TRTPN*ATPTN	Plac	0	Plac	3	1175.10	1790.13	422	0.66	0.5119	0.05	-2343.58	4693.78
TRTPN*ATPTN	Plac	0	Plac	4	-4.1324	1790.13	422	-0.00	0.9982	0.05	-3522.81	3514.55
TRTPN*ATPTN	Plac	0.5	Plac	1	-951.50	1790.13	422	-0.53	0.5953	0.05	-4470.18	2567.18
TRTPN*ATPTN	Plac	0.5	Plac	2	3114.80	1790.13	422	1.74	0.0826	0.05	-403.88	6633.48
TRTPN*ATPTN	Plac	0.5	Plac	3	2700.73	1790.13	422	1.51	0.1321	0.05	-817.95	6219.41
TRTPN*ATPTN	Plac	0.5	Plac	4	1521.49	1790.13	422	0.85	0.3958	0.05	-1997.18	5040.17
TRTPN*ATPTN	Plac	1	Plac	2	4066.30	1790.13	422	2.27	0.0236	0.05	547.62	7584.98
TRTPN*ATPTN	Plac	1	Plac	3	3652.23	1790.13	422	2.04	0.0420	0.05	133.55	7170.91
TRTPN*ATPTN	Plac	1	Plac	4	2473.00	1790.13	422	1.38	0.1679	0.05	-1045.68	5991.68
TRTPN*ATPTN	Plac	2	Plac	3	-414.07	1790.13	422	-0.23	0.8172	0.05	-3932.75	3104.61
TRTPN*ATPTN	Plac	2	Plac	4	-1593.30	1790.13	422	-0.89	0.3739	0.05	-5111.98	1925.38
TRTPN*ATPTN	Plac	3	Plac	4	-1179.23	1790.13	422	-0.66	0.5104	0.05	-4697.91	2339.44

Tests of Effect Slices

Effect	Analysis Timepoint (N)	Num DF	Den DF	F Value	Pr > F
TRTPN*ATPTN	0	5	422	0.61	0.6906
TRTPN*ATPTN	0.5	5	422	3.11	0.0090
TRTPN*ATPTN	1	5	422	3.97	0.0016
TRTPN*ATPTN	2	5	422	2.84	0.0155
TRTPN*ATPTN	3	5	422	1.55	0.1719
TRTPN*ATPTN	4	5	422	1.75	0.1215

Appendix 16.1.9.2.4
Statistical Methods and Analysis Output Supporting Table 14.2.5
Supporting Table 14.2.4

The Mixed Procedure

Parameter Code=MVMIPM