16.1.9 Documentation of Statistical Methods

16.1.9.1 Statistical Analysis Plan

STATISTICAL ANALYSIS PLAN

A Randomized, Open-Label, Single Oral Dose, Three-Way Cross-Over Trial to Evaluate the Relative Bioavailability of CVN424 Suspension and Tablet Formulations Including an Assessment of the Effect of Food on the Tablet Formulation in Healthy Adult Volunteers

Protocol No: CVN424-102
Final Protocol Date: 30 August 2022
Protocol Clarification Letter 1: 30 September 2022
Protocol Clarification Letter 2: 20 October 2022
Protocol Clarification Letter 3: 21 October 2022
Compound Name: CVN424

Celerion Project CA38736
Final Version 1.0
Date: 21 December 2022

Cerevance Beta, Inc.
One Marina Park Drive, Suite 1410, Boston, MA 02210

Celerion
621 Rose Street, Lincoln, NE 68502

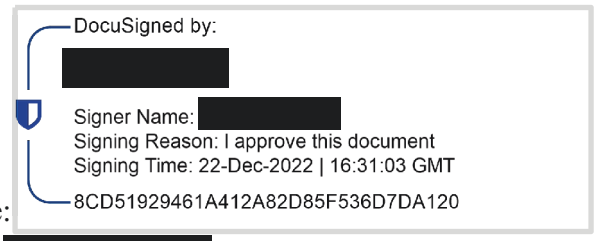
STATISTICAL ANALYSIS PLAN SIGNATURE PAGE

Compound Name: CVN424

Protocol: CVN424-102

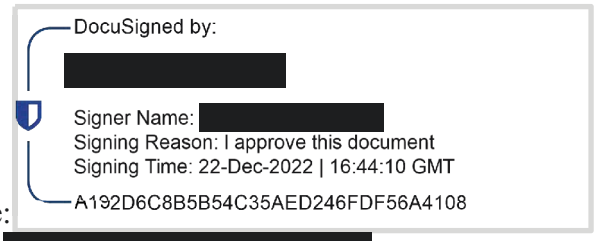
Study Title: A Randomized, Open-Label, Single Oral Dose, Three-Way Cross-Over Trial to Evaluate the Relative Bioavailability of CVN424 Suspension and Tablet Formulations Including an Assessment of the Effect of Food on the Tablet Formulation in Healthy Adult Volunteers

Issue Date: 21 December 2022

Signature: 

Date: _____

[redacted] MS
Senior Director, Biostatistics
Clinical Pharmacology
Celerion, Lincoln, NE

Signature: 

Date: _____

[redacted] PharmD, MS (Authorized Designate)
[redacted] PhD
Pharmacokinetic Scientist I, Clinical Pharmacology and Pharmacometrics, Data Management and Biometrics
Celerion, Lincoln, NE

STATISTICAL ANALYSIS PLAN SIGNATURE PAGE

Compound Name: CVN424

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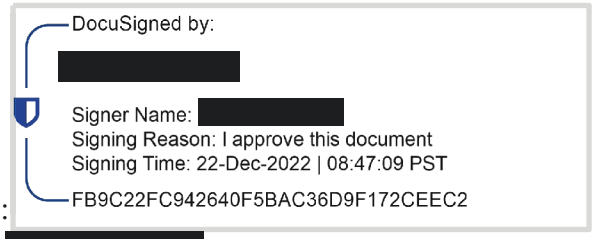
Signature: 

Date: _____

[redacted] MD
Chief Medical Officer
Cerevance, Inc.

TABLE OF CONTENTS

1. INTRODUCTION

The following statistical analysis plan (SAP) provides the framework for the analysis and presentation of the data from this study. Any changes made from the planned analysis described in the protocol or after finalization of this SAP will be documented in the Clinical Study Report (CSR). The section referred to as "Table, Figure, and Listing Shells" within this SAP describes the Clinical Data Interchange Standards Consortium (CDISC) input in order to provide traceability to the corresponding tables, figures, and listings (TFLs). Analysis data model (ADaM) is the source for tables and figures (as well as listings that may contain derived data) and study data tabulation model (SDTM) is the source for the data listings.

Any additional exploratory analyses not addressed within this SAP and/or driven by the data, or requested by Cerevance Beta Inc., will be considered out of scope and must be described in the CSR.

2. OBJECTIVES AND ENDPOINTS

Objectives	Endpoints
Primary	
• To determine the relative bioavailability (BA) of 150 mg of CVN424 administered in a single dose of suspension formulation compared to 150 mg tablet. .	• The relative bioavailability of the CVN424 suspension in the fasted state, and CVN424 tablet formulation in the fasted and fed state based on maximum observed plasma concentration (C_{max}), time to reach C_{max} (T_{max}), and area under the plasma concentration time curve from time 0 to 96 hours (AUC_{0-96h}) which is the primary area PK parameter. • The ratio of the pharmacokinetic (PK) parameters between CVN424 suspension and tablet in the fasted and fed state will be calculated and summarized descriptively. In addition, an analysis of variance (ANOVA) on log-transformed PK parameters (AUC_{0-t}, AUC_{0-96h}, C_{max}) will be performed. Ratios of geometric means and 90% confidence intervals will be calculated. T_{max} will be compared between CVN424 suspension and CVN424 tablet with and without food.

Secondary	
• To establish the effects of food (FE) on the rate and extent of absorption of CVN424 150 mg tablet when administered in fed conditions compared to administration under fasting conditions.	• The ratio of the PK parameters between CVN424 tablets in the fed and fasted state will be calculated and summarized descriptively. In addition, an analysis of variance (ANOVA) on log-transformed PK parameters (AUC_{0-t}, AUC_{0-96h}, C_{max}) will be performed. Ratios of geometric means and 90% confidence intervals will be calculated. T_{max} and T_{lag} will be compared between CVN424 tablets in the fed and fasted state.
• To assess the safety of the tablet under fast and fed conditions and suspension under fast conditions	• Treatment-emergent adverse events (TEAEs) and tolerability as measured by discontinuations (D/Cs) due to adverse event (AE).
Exploratory*	
• Explore serum/plasma (e.g., potential characterization of drug metabolites) that may contribute to variability in CVN424.	• Potentially characterize metabolic enzyme and transporter polymorphisms.
• Assessment of urine concentrations and volumes to enable calculation of urine PK parameters where possible.	• Urine concentrations and volumes of CVN424 tablet formulation at pre-dose and 0-12, 12-24, 24-48, 48-96 hours post-dose. Urine PK parameters (cumulative amount of unchanged drug excreted into the urine [Ae], fraction of unchanged drug excreted in the urine [fe], and renal clearance [CL_R]) to be determined where possible.

*Metabolites will not be investigated in plasma and urine as part of the SAP. If AUC_{0-t} equals AUC_{0-96h}, only AUC_{0-96h} will be presented.

3. STUDY DESIGN

This study is designed to meet the objective(s) outlined in Section 2.

This is a randomized, open-label, single-oral dose, three-way cross-over study under fasted and fed conditions, in healthy participants.

32 healthy male or female participants will be enrolled in 1 of 6 single-dose, three-way cross-over sequences. Sequences 1, 3, 4, and 5 will have 5 participants each, and Sequences 2 and 6 will have 6 participants each. Please see the study schema below:

Sequence	Dosing #1 (Period 1 Day 1)		Dosing #2 (Period 2 Day 1)		Dosing #3 (Period 3 Day 1)
1 (n=5)	Suspension (fasted)		Tablet (fasted)		Tablet (fed)
2 (n=6)	Tablet (fasted)		Tablet (fed)		Suspension (fasted)
3 (n=5)	Tablet (fed)	Washout	Suspension (fasted)	Washout	Tablet (fasted)
4 (n=5)	Suspension (fasted)		Tablet (fed)		Tablet (fasted)
5 (n=5)	Tablet (fasted)		Suspension (fasted)		Tablet (fed)
6 (n=6)	Tablet (fed)		Tablet (fasted)		Suspension (fasted)

Each sequence will proceed through three cross-overs (suspension-fasted, tablet-fed, tablet-fasted) according to the schematic above, with dosing to occur on Day 1 of each of the three periods. Participants in the fasted portion of each sequence will be dosed under overnight fasted conditions and will remain fasted for 4 hours post-dose. Water consumption is permitted as desired except for 1 hour before and after administration of Study Drug.

To assess the effect of food on CVN424 bioavailability in tablet formulation, the single-dose administration will be administered after ingestion of a standardized high-fat, high-calorie meal according to FDA Guidance for Industry (Food-effect (FE) bioavailability and fed bioequivalence studies, Jun 2022).

Participants for all sequences will be admitted to the study unit 1 day prior to dosing and remain in the unit for safety and PK assessments through 96 hours post-dose. The total confinement for each period will be 5 nights per sequence (15 days total) unless extended at the discretion of the Investigator, e.g., for monitoring and/or management of AEs.

Once 96-hour post-dose PK has been collected, participants will be discharged from the unit for the remainder of the washout period and return the day prior to their next scheduled dosing period.

4. ANALYSIS POPULATIONS

Safety Set

The Safety Analysis Set will consist of all participants who are enrolled and receive study drug. Participants in this analysis set will be used for demographic, baseline characteristics, and safety summaries.

Pharmacokinetic Set

The PK set will consist of all participants who receive study drug and have at least 1 measurable plasma concentration.

If any participants are found to be non-compliant with the dosing schedule or with incomplete data, a decision will be made on a case-by-case basis as to their inclusion in the analysis but will be presented in the participant listings.

5. TREATMENT DESCRIPTIONS

Treatment A will be supplied as 150 mg CVN424 suspension.

Treatments B and C will be supplied as 150 mg CVN424 tablets.

For the Suspension (fasted) and Tablet (fasted) portions: Breakfast will not be provided on dosing days. Participants must fast for a minimum of 4 hours after dose administration unless otherwise indicated. CVN424 will be administered with approximately 240 mL of water after a fast of at least 10 hours. Participants will continue to fast for an additional 4 hours after dosing and eat lunch following the 4-hour PK blood collection. Participants may consume water ad libitum except for 1 hour before and 1 hour after drug administration.

For the Tablet (fed) portion (food effect): CVN424 will be administered after ingesting a standardized high-fat, high-calorie meal according to FDA Guidance for Industry (Food-effect bioavailability and fed equivalence studies, June 2022). Participants will finish their breakfast in its entirety within 30 minutes and will receive an investigational product 30 minutes (±5 minutes) after beginning the meal. The meal start and stop times, and percentage of the meal consumed will be recorded in the source, and the appropriate case report form (CRF) for all meals served on dosing days.

The treatments descriptions would be described as:

Treatment	Short Description	Long Description
Treatment A	Suspension-Fasted	a single oral dose of 150 mg CVN424 suspension under fasted condition

Treatment	Short Description	Long Description
Treatment B	Tablet-Fasted	a single oral dose of 150 mg CVN424 tablet under fasted condition
Treatment C	Tablet-Fed	a single oral dose of 150 mg CVN424 tablet under fed condition

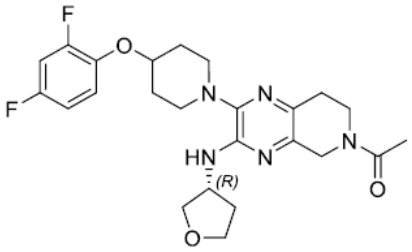
6. PHARMACOKINETIC ANALYSIS

6.1 Investigational Product and Pharmacokinetic Analyte Information

The analyte, CVN424, can be described with the following structure and molecular weight (MW) of 473.52 g/mol (Figure 6-1).

Plasma and urine CVN424 concentrations will be analyzed. As the amount of CVN424 to be dosed corresponds to the described dose, no corrections will be needed for any dose-dependent PK parameters.

Figure 6-1: CVN424 (MW = 473.52 g/mol)



6.2 Bioanalytical Method

Plasma and urine concentrations of CVN424 will be determined using high performance liquid chromatography-tandem mass spectrometry (HPLC/MS-MS) method validated with respect to accuracy, precision, linearity, sensitivity, and specificity at Frontage Laboratories, Inc. The analytical range (lower limit of quantitation [LLOQ] – upper limit of quantitation [ULOQ]) for CVN424 in plasma and urine are both expected to be 1 – 1000 ng/mL.

6.3 Pharmacokinetic Concentrations

Measurements and Collection Schedule

Collection of Blood for PK Sampling

Blood samples for analysis of CVN424 plasma concentrations will be collected into chilled Vacutainers containing K_2EDTA. Instructions for sample processing and shipment are

provided in a separate lab manual. In all treatments, serial blood samples to determine CVN424 concentrations in plasma will be collected according to the Schedule of Study Procedures. The PK samples will be collected at the nominal time point: Predose (within 15 minutes prior to dosing; 60 minutes for the fed treatments), 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, 48, 60, 72, 84 and 96 h; all other assessments will be collected, before or after, within the allowable windows. The actual time of sample collection will be recorded on the source document and CRF. Sampling time points may be adjusted or added based on the preliminary emerging PK data collected from prior sequence(s).

Collection of Urine for PK Sampling

In Tablet-Fasted treatment only, urine samples for analysis of CVN424 (or its metabolites) concentration in urine will be collected: pre-dose (within 12 hours prior to dosing), 0-12, 12-24, 24-48, and 48-96-hours post-dose. Volume of urine collected is to be recorded. Instructions for sample processing and shipment are provided in a separate lab manual.

All concentration data will be listed by participant, treatment, and nominal time in an appendix. If there are any significant protocol deviations (e.g., significant time deviations from nominal sample times), some individual concentration data may be excluded from mean data presentations (e.g., descriptive statistics for concentrations at specific nominal time points and mean concentration-time plots). All deviations and excluded data will be provided and discussed in the CSR.

6.4 Noncompartmental Pharmacokinetic Analysis and Parameter Calculation

6.4.1 Plasma Pharmacokinetic Parameters

Plasma concentrations of CVN424 as determined per the bioanalytical method and the collection times described in Section 6.2 and Section 6.3, respectively, will be used for the calculation of the plasma CVN424 PK parameters.

The appropriate noncompartmental PK parameters will be calculated from the plasma CVN424 concentration-time data using Phoenix® WinNonlin® Version 8.3.4 or higher. Actual sample times will be used in the calculations of the PK parameters. The calculation of the actual time for CVN424 will be in respect to the dose administration time of CVN424 on Day 1. All PK parameters included in the protocol are listed in Table 6–1 below, and are defined as appropriate for study design.

Table 6–1 Noncompartmental Plasma CVN424 Pharmacokinetic Parameters to be Calculated

Parameter	Label to be Used in the Text, Tables, and Figures	Definition	Method of Determination
$AUC_{0\text{-}inf}$	AUC0-inf	Area under the concentration-time curve from time 0 extrapolated to infinity	$AUC_{0\text{-}inf} = AUC_{0\text{-}t} + (C_{last}/Kel)$ where Clast is the last observed/measured concentration
$AUC_{0\text{-}t}$	AUC0-t	Area under the concentration-time curve from time 0 to the time of the last observed/measured non-zero concentration	Calculated using the Linear Trapezoidal with Linear Interpolation Method
$AUC_{0\text{-}96h}$	AUC0-96h	Area under the concentration-time curve from time 0 to 96 hours postdose. This parameter may be interpolated or extrapolated (primary PK area parameter).	Calculated using the Linear Trapezoidal with Linear Interpolation Method
$AUC_{\%extrap}$	AUC%extrap	Percent of $AUC_{0\text{-}inf}$ extrapolated, represented as $(1 - AUC_{0\text{-}t}/AUC_{0\text{-}inf})*100$	$AUC_{\%extrap} = (1- AUC_{0\text{-}t}/AUC_{inf}) \times 100$
C_{max}	Cmax	The maximum observed concentration	Taken directly from bioanalytical data
CL/F	CL/F	The apparent total plasma clearance after oral administration	$CL/F = Dose/(AUC_{0\text{-}inf})$
K_{el}	Kel	Apparent first-order terminal elimination rate constant	Calculated by linear least-squares regression analysis using the maximum number of points in the terminal log-linear phase (e.g., 3 or more non-zero concentrations)
T_{lag}	Tlag	Lag time – the time delay between drug administration and the onset of absorption; where onset of absorption could be defined as the time point prior to the first observed/measured non-zero plasma concentration.	Taken from clinical database as the difference in the time of administration and the time of the associated blood draw. Report actual time per individual, as opposed to nominal time.
T_{max}	Tmax	The time to reach C_{max}; if C_{max} occurs at more than one time point, T_{max} is defined as the first time point with this value	Derived from clinical data as the difference in the time of the blood draw which is associated with the C_{max} and the time of administration
$t_{½}$	t½	Apparent first-order terminal elimination half-life	$t½ = 0.693/Kel$

Parameter	Label to be Used in the Text, Tables, and Figures	Definition	Method of Determination
V_z/F	Vz/F	The apparent volume of distribution during the terminal elimination phase after oral administration	V_z/F = Dose/($AUC_{0\text{-}inf} \times$ Kel)

*In the text of the CSR, subscripts will be used in parameter names, as appropriate. However, in post-text tables and listings, subscripts will not be used in parameters. $AUC_{0\text{-}inf}$ will not be discussed in CSR and will not be presented in in-text tables. If $AUC_{0\text{-}t}$ equals $AUC_{0\text{-}96h}$, then only $AUC_{0\text{-}96h}$ will be presented and the corresponding footnote will be added.

PK parameters will not be calculated for participants with less than 3 consecutive postdose time points with quantifiable concentrations. Participants for whom there are insufficient data to calculate the PK parameters will be included in the concentration tables and individual concentration-time figures only and excluded from the summaries and statistical analysis.

For the calculation of the PK parameters, plasma concentrations below the limit of quantitation (BLQ) prior to the first quantifiable concentration will be set to 0 and plasma concentrations BLQ after the first quantifiable concentration will be treated as missing.

The K_{el} will be determined using linear regressions composed of at least 3 data points. Furthermore, the K_{el} will not be assigned if 1) the terminal elimination phase is not apparent, 2) T_{max} is one of the last 3 data points, or 3) the R^2 value is less than 0.75. In cases where the Kel interval is not assigned, the values of K_{el} and K_{el}-dependent parameters (i.e., $t_{½}$, $AUC_{0\text{-}inf}$, CL/F, and V_z/F) are considered not calculable and will not be reported. Wherever the resulting $t_{½}$ is more than half as long as the sampling interval, the Kel value and Kel-dependent parameters (i.e., $t_{½}$, $AUC_{0\text{-}inf}$, CL/F, and V_z/F) may be flagged and presented, as judged appropriate and in accordance with Celerion SOPs.

Wherever the $AUC_{\%extrap}$ is greater than 20%, the K_{el} value and K_{el}-dependent parameters (i.e., $t_{½}$, $AUC_{0\text{-}inf}$, CL/F, and V_z/F) will not be reported.

All available data will be included in the concentration and PK parameter tables to the extent possible. Data for each participant will be included in the summary statistics and statistical comparisons of PK parameters with the exceptions described as follows:

- Data from participants who experience emesis at or before 2 times median T_{max} for the given treatment during the PK sampling period time course of the study for CVN424 will be excluded from the summary statistics and statistical comparisons of PK parameters for the given treatment.

- Data from subjects who violate a protocol inclusion or exclusion criteria or deviate from the protocol define procedures that are deemed important a priori, or have unavailable or incomplete data which may influence the PK analysis will be excluded from the summary

statistics and statistical comparisons of PK parameters (entirely or for a given treatment, as appropriate).

- If predose concentrations > 5% of Cmax are observed, the affected participant's concentration and PK parameter data will be excluded from the summary statistics and statistical comparisons of PK parameters for the given treatment.

6.4.2 Urine Pharmacokinetic Parameters

The following PK parameters will be calculated from urine CVN424 data using Phoenix® WinNonlin® and SAS®. All PK parameters included in the protocol are listed in Table 6–2 below, and are defined as appropriate for study design.

Table 6–2 Noncompartmental Urine Pharmacokinetic Parameters to be Calculated

Parameter	Label to be Used in Text, Tables, and Figures	Definition	Method of Determination
$Ae_{,t1-t2}$	Ae,t1-t2	Amount of CVN424 excreted in each postdose urine collection interval (t1 to t2, t2 to t3, etc.)	Ae,t1-t2 = (Cur,t1-t2 × Vur, t1-t2)
Ae	Ae	Cumulative amount of CVN424 excreted in the urine through urine collection interval	Calculated as: Ae = Ae,t1-t2 + Ae,t2-t3 … + Ae,t(n-1)-tn where t1 = 0 and tn = the end of the last collection interval
fe	fe	Fraction of dose excreted CVN424 into urine within each postdose urine collection interval	Calculated as [Ae]/Dose
CL_R	CL_R	Renal clearance (overall interval only)	CLr = Ae/AUC where Ae (urine) and AUC (plasma) are determined over a time-matched interval (i.e., from time 0 to the latest interval with quantifiable concentrations in both urine and plasma, by participant)

*In the text of the CSR or report, subscripts will be used in parameter names, as appropriate.

For the calculation of urine PK parameters, urine concentrations BLQ will be set to zero (0) and the amount and fraction excreted in the urine for the respective collection interval will be estimated as zero (0). Cumulative urine PK parameters (e.g., Ae) and derived parameters (e.g., fe) after a missing sample (e.g., lost part of void, volume not recorded) will be presented (as underestimated), but may be excluded from summary statistics, if warranted. In

the case of no void during a given interval, cumulative parameters and derived cumulative parameters will be carried forward from the previous (postdose) interval to the given interval (or set to zero [0] if there is not a previous postdose interval with quantifiable data).

6.5 Data Summarization and Presentation

All CVN424 PK concentrations and/or PK parameters descriptive statistics will be generated using SAS® Version 9.4 or higher.

The plasma and urine concentrations of CVN424 will be listed and summarized by treatment and time point for all participants in the PK Set. Plasma and urine concentrations of CVN424 will be presented with the same level of precision as received from the bioanalytical laboratory. Summary statistics, including sample size (n), arithmetic mean (mean), standard deviation (SD), coefficient of variation (CV%), standard error of the mean (SEM), minimum, median, and maximum will be calculated for all nominal concentration time points. Excluded participants will be included in the concentration listings, but will be excluded from the summary statistics and noted as such in the tables. All BLQ values will be presented as "BLQ" in the concentration listings and tables but will be set to zero (0) or missing as described in Sections 6.4.1 and 6.4.2, for each matrix and footnoted accordingly.

For urine collected over intervals, only concentration and volume parameters will be presented for the predose collection interval.

Plasma mean and individual concentration-time profiles will be presented on linear and semi-log scales. Individual concentration-time profiles will be based on actual sample times, and mean concentration-time profiles will be based on nominal sample times. When there are significant time deviations from nominal sample time points, some concentrations may be excluded from the summary statistics and any corresponding summary figures.

Urine mean cumulative CVN424 excretion profiles will be presented on linear scale. Linear mean plots will be presented with and without SD.

Plasma CVN424 PK parameters, including individual treatment ratios, will be listed and summarized by treatment for all participants in the PK Set. PK parameters will be reported to 3 significant figures for individual parameters, with the exception of C_{max}, which will be presented with same level of precision as received from the bioanalytical laboratory and T_{max}, T_{lag} which will be presented with 2 decimal places. Summary statistics (n, mean, SD, CV%, SEM, minimum, median, maximum, geometric mean (Geom Mean) and geometric CV% (Geom CV%)) will be presented for all PK parameters. Excluded participants will be listed in the PK parameter tables, but will be excluded from the summary statistics and noted as such in the tables.

Urine CVN424 PK parameters will be listed and summarized using descriptive statistics (n, mean, SD, CV%, SEM, minimum, median, and maximum) for the PK Set. Excluded participants will be listed in the urine PK tables, but will be excluded from the summary

statistics and noted as such in the tables. Urine concentrations that are BLQ will be presented as "BLQ" in the listings and treated as zero (0) for the calculation of summary statistics.

The level of precision for each concentration and PK parameter statistic will be presented as follows: minimum/maximum in same precision as in bioanalytical data and/or parameter output, mean/median/Geom Mean in one more level of precision than minimum/maximum, SD/SEM in one more level of precision than mean/median/Geom Mean, n will be presented as an integer, and CV%/Geom CV% will be presented to the nearest tenth.

6.6 Statistical Analysis of PK Parameters

A comparison of the natural-log (ln)-transformed PK parameters $AUC_{0\text{-}t}$, $AUC_{0\text{-}96h}$, $AUC_{0\text{-}inf}$ and C_{max} will be made to evaluate the relative bioavailability of CVN424 Tablet-Fasted versus Suspension-Fasted and Table-Fed versus Suspension-Fasted; Tablet-Fed versus Tablet-Fasted for evaluation of the FE by performing an analysis of variance (ANOVA) model using SAS® PROC MIXED. The ANOVA model will include treatment, period, and sequence as fixed effects and participant nested within sequence as a random effect. The geometric least squares mean (LSM) values reported in the statistical comparisons will be the exponentiated LSMs from the ANOVA. The geometric ratio of the LSMs will be calculated from the exponentiated difference between the treatment LSMs from the ANOVA analysis. The 90% confidence intervals (CIs) for the ratios will be derived by exponentiation of the CIs obtained for the difference between the treatment LSMs. The CIs will be expressed as a percentage relative to the reference treatment.

The comparisons of interest are as follows:

- BA Assessment:
    - Treatment B (Tablet-Fasted, test) compared with Treatment A (Suspension-Fasted, reference)
    - Treatment C (Tablet-Fed, test) compared with Treatment A (Suspension-Fasted, reference)
- Food Effect (high-fat, high-calorie meal): Treatment C (Tablet-Fed, test) compared with Treatment B (Tablet-Fasted, reference)

Similar BA criteria will be met if the 90% CIs for the ratios of LSMs of ln-transformed $AUC_{0\text{-}t}$, $AUC_{0\text{-}96h}$, and C_{max} of CVN424 fall within 80.00 and 125.00% (Tablet- Fasted versus Suspension-Fasted; Tablet- Fed versus Suspension-Fasted).

The lack of a food effect will be concluded if the 90% CIs for the ratios of LSMs of ln-transformed $AUC_{0\text{-}t}$, $AUC_{0\text{-}96h}$, and C_{max} of CVN424 fall between 80.00 and 125.00% (Tablet-Fed versus Tablet-Fasted).

The ANOVA analysis will be performed using the following SAS® code:

```
PROC MIXED;
CLASS TREATMENT PARTICIPANT PERIOD SEQUENCE;
MODEL ln(PK_PARAMETER) = TREATMENT PERIOD SEQUENCE / DDFM=KR;
```

```
RANDOM PARTICIPANT(SEQUENCE);
ESTIMATE “Tablet-Fasted vs Suspension-Fasted” TREATMENT -1 1 0 / cl alpha=0.1 e;
ESTIMATE “Tablet-Fed vs Suspension-Fasted” TREATMENT -1 0 1 / cl alpha=0.1e;
ESTIMATE “Tablet-Fed vs Tablet-Fasted” TREATMENT 0 -1 1 / cl alpha=0.1 e;
LSMEANS TREATMENT / cl alpha=0.1;
RUN;
```

Geometric LSMs will be presented in one more precision level than the associated PK parameter. GMRs and 90% CIs will be presented with 2 decimal places and intra-participant CV% will be presented to 2 decimal places.

Nonparametric Analysis

For Tmax and Tlag, nonparametric comparison between treatments B vs A (and C vs B) will be performed using Walsh Averages and Wilcoxon Signed-Rank Test Statistic. The median difference and the 90% CI of the median difference in Tmax and Tlag will be estimated. Significant differences in Tmax and Tlag values for the treatment comparison will be concluded if the resulting $p < 0.05$.

6.7 Interim Analysis

Interim analysis will be conducted for plasma data in Period 1, 2 and 3 and details of the interim analysis are described in a separate document.

7. SAFETY

All safety data will be listed by participant and chronologically by assessment time point. This will include rechecks, unscheduled, and early termination assessments. Data for participants who screen failed will be listed in separate appendices.

Applicable continuous variables will be summarized using n, mean, SD, minimum, median, and maximum.

The level of precision will be presented as follows: minimum/maximum in the same precision as in the database, mean/median in one more precision level than minimum/maximum, SD in one more precision level than mean/median, and n will be presented as an integer. Percentages will be presented as an integer.

Where individual data points are missing because of dropouts or other reasons, the data will be summarized based on reduced denominators.

Baseline will be the result closest and prior to the dose in the respective period unless otherwise stated. Summaries for post-baseline time points will not include rechecks, unscheduled, or early termination measurements.

Tables summarizing safety data by assessment time point will only include summaries for baseline and post-baseline time points.

7.1 Participant Disposition

Participants will be summarized by the number and percent of participants dosed, completed the study, discontinued the study (with discontinuation reasons), completed treatment, and discontinued from treatment (with treatment discontinuation reasons) by randomized treatment sequence and overall.

Individual participant dosing status (i.e., which treatments were administered to each participant) will also be provided along with their study completion status and date of study completion or discontinuation. The number of participants dosed for each treatment will also be presented.

7.2 Protocol Deviations

Protocol deviations are captured by the clinical site and provided in the CSR in a similar format to that provided by the clinical site. Protocol deviations are not edited or processed in SAS®.

7.3 Demographics

Descriptive statistics will be calculated for continuous variables (age, body mass index, height, and weight) by randomized treatment sequence and overall. Age will be approximated by subtracting the year of birth from the year of informed consent. If year of informed consent – year of birth is one more than the protocol maximum age then the age approximation will be year of informed consent – year of birth – 1. Descriptive statistics for body mass index, height, and weight will be calculated using screening measurements.

Frequency counts will be provided for categorical variables (sex, race, and ethnicity) for each randomized treatment sequence and overall.

7.4 Adverse Events

All AEs occurring during this clinical trial will be coded using the Medical Dictionary for Regulatory Activities (MedDRA®), Version 25.1.

All AEs captured in the database will be listed in a by-participant data listing including verbatim term, coded term, treatment, onset date/time, resolution date/time, frequency, severity, relationship to study product, relationship to study procedure, and action; however, only TEAEs will be summarized.

A TEAE is defined as an AE that is starting at the time of or after study product administration and within 30 days after the final dose (onset date – last dose date + 1 ≤ 30). Each TEAE will be attributed to a treatment based on the onset date and time of the AE compared to that of the respective treatment administration date and time. An AE that occurs during the washout period between treatments will be considered treatment-emergent to the last treatment administered prior to onset of the AE.

If the onset time of an AE is missing and the onset date is the same as the treatment dosing date, then the AE will be considered treatment emergent in the prior and current treatment. If the onset time of an AE is missing and the onset date does not fall on a treatment dosing date, then the AE will be considered treatment emergent for the last treatment administered. If the onset date of an AE is missing, then the AE will be considered treatment emergent and attributed to each treatment on the study, unless the onset date is known to have occurred within or between specific treatment periods.

TEAEs will be tabulated by System Organ Class (SOC) and Preferred Term. Summary tables will include the number of participants reporting the TEAE and as a percent of the number of participants dosed by treatment and overall. The number of TEAEs will be tabulated in a similar manner. A table, which summarizes the number of TEAEs by Preferred Term, severity, and relationship to study product, will also be included.

Serious adverse events (SAEs), if present, will also be listed. Applicable narratives will be included in the CSR.

7.5 Clinical Laboratory Tests (Serum Chemistry, Hematology, Coagulation and Urinalysis)

Clinical laboratory tests will be measured at the following time points:

Clinical Laboratory Panels	**Time Point**		
	Period	CRF/Listing Day and Hour	Table
Serum Chemistry, Hematology, Coagulation, Urinalysis	Screening		NA
	1, 2, 3	Day -1 Hour -26.25, -25.75 Day 1 Hour -2.00, -1.75 Day 2 Hour 23.77*^ Day 3 Hour 48.00^ Day 5 Hour 95.77*, 96.00	NA Baseline Day 2^ Day 3^ Day 5

Time points in the CRF/Listing column are approximated/based on the blank CRF and it should be noted that the data listings will reflect the data found in the final participant CRFs.
If applicable, an early termination assessment will be performed.
NA = Not applicable; *Period 2 is at X.75 instead of X.77, ^Urinalysis is not collected on Days 2 and 3.

Clinical laboratory results will be presented as extracted from the clinical laboratory database. Out-of-reference range flags will be recorded as follows: high (H) and low (L) for numerical results and did-not-match (*) for categorical results.

Out-of-reference range values and corresponding recheck results will be listed. Out-of-range clinical laboratory values which are deemed clinically significant will be entered, listed, and summarized with the AEs.

Clinically significant labs would be denoted as AEs and listed/summarized as such.

For all numeric laboratory values, descriptive statistics will be presented for each laboratory test by assessment time point and treatment. Change from baseline will be summarized in a

similar manner. In line with the protocol, an overall column will also be included for these descriptive statistics for which the baseline will still be the treatment specific baselines. For all numeric laboratory tests, the mean value calculated for each assessment time point and treatment will be compared to the reference range and flagged if outside of the reference range (* if above the reference range and ^ if below the reference range). In the event there is more than one reference range for a laboratory test, the comparison will be made against the lowest of the lower ranges and the highest of the higher ranges.

For each laboratory test, a shift table will be developed to compare the frequency of the results at baseline (above reference range, within reference range, or below reference range) with the respective postdose results by treatment. For urinalysis tests, the categories are within reference range and outside reference range.

7.6 Vital Signs

Vital signs will be measured at the following time points:

Parameter	Time Point		
	Period	CRF/Listing Day and Hour	Table
Orthostatic [Blood Pressure and Heart Rate]. Respiration, Temperature	Screening		NA
	1, 2, 3	Day -1 Hour -24.83 Day 1 Hour -0.83 Day 1 Hour 1.63* Day 2 Hour 24.08 Day 3 Hour 48.08 Day 4 Hour 72.08 Day 5 Hour 96.08	NA Baseline Hour 1.5* Day 2 Day 3 Day 4 Day 5
Weight	Screening		NA (summarized in demographics)
	3	Day 5 Hour 96.25	NA

Time points in the CRF/Listing column are approximated/based on the blank CRF and it should be noted that the data listing will reflect the data found in the final participant CRFs.
Heart rate is labeled as pulse in the CRF.
If applicable, an early termination assessment will be performed.
NA = Not applicable
*Periods 2 and 3 only

Per protocol, the supine measurements are sometimes collected in triplicate. In these cases, the averaged (to the nearest tenth) of the supine measurements, collected within 15-minute window prior to the standing measurements will be used in all summaries. In the case that there are more than 3 collected in the 15-minute window, the 3 records closet to the standing will be used in the average. For time points when averages are derived, the averages will be summarized instead of the individual measurements.

Descriptive statistics will be presented for vital signs measurements by assessment time point and treatment. Change from baseline will be summarized in a similar manner. An across

summary treatment column will be included but it should be noted that the change from baseline will be treatment specific change.

Orthostatic change will be calculated for blood pressure and heart rate at the time points listed by subtracting the supine (or average supine, as applicable) measurement from the standing measurement (i.e. orthostatic change = standing measurement – supine measurement). Descriptive statistics will be presented for each orthostatic vital sign parameter by assessment time point and treatment. Change from baseline will be summarized in a similar manner. Similar to the vital sign summaries, an overall column will be included. Baseline will typically be the orthostatic change result obtained prior to dosing on Day 1 of each period. Any standing vital sign measurement collected more than 15 minutes after the corresponding supine (or average, as applicable) measurement will be excluded from analysis. At postdose time points, the first complete orthostatic assessment (i.e. assessment with supine result(s) and corresponding standing result) will be used during analysis. If the first complete orthostatic assessment is not the original assessment at a given postdose time point (e.g., original assessment has supine result(s) and no corresponding standing result), the first complete orthostatic assessment will only be used during analysis if this assessment starts within 30 minutes of the original incomplete assessment. Other postdose unscheduled and early termination measurements will not be included in orthostatic vital sign summaries.

Abnormal vital signs which are deemed clinically significant will be entered, listed, and summarized with the AEs.

7.7 Electrocardiogram

ECGs will be measured in triplicate at the following time points:

Parameter	Time Point		
	Period	CRF/Listing Day and Hour	Table
HR, PR, QRS, QT, QTcB, QTcF, and RR	Screening		NA
	1, 2, 3	Day 1 Hours -0.98, -0.97, -0.95 Day 1 Hours 2.75, 2.77, 2.78	Baseline Hour 3
	3	Day 5 Hours 95.67, 95.68, 95.70	Day 5

Time points in the CRF/Listing column are approximated/based on the blank CRF and it should be noted that the data listing will reflect the data found in the final participant CRFs.
If applicable, an early termination assessment will be performed.
NA = Not applicable; Day 5 will have a reduced sample size given it was only measured on Period 3.

ECGs will be collected in triplicate. The triplicate measures will be averaged and rounded to the nearest tenth. The averages will be used in all summaries.

Only valid ECGs will be used to calculate average ECG values for each parameter that will be used in the analysis. Valid ECGs do not include records of questionable quality. These include, but are not limited to, records with an associated comment indicating an artifact, lead reversal, wandering lead, etc. ECGs collected in error will also not be classified as valid ECGs. After excluding these ECGs, the remaining ECGs for the respective triplicate set will

be assessed against a time window of 10 minutes. ECGs that fall outside of the 10-minute window will not be considered valid ECGs. At a given time point, if it is not possible to form a complete ECG triplicate set of valid results, the average will be calculated using the available valid results, i.e., the average of 2 valid ECGs or the single valid ECG result will be used in the analysis. Averaged ECG values will be displayed to the nearest tenth and used in the analysis.

Descriptive statistics will be presented for the by-participant averages of each ECG parameter by assessment time point and treatment. Change from baseline will be summarized in a similar manner. An overall column will be included to pool all treatment data together. At postdose time points, the average of the first valid ECG set will be used in the analysis. Outside of this requirement, postdose unscheduled and early termination measurements will not be included in summaries.

The ECG interpretation (within normal limits, abnormal-not clinically significant, abnormal-clinically significant) will be tabulated by assessment time point and treatment. The worst result in the triplicates will be used for these tabulations.

All ECG data will be listed by participant and QTc values > 450 msec will be flagged. A separate by participant listing will be provided to display the ECG average values to be used during analysis where QTc average values > 450 msec and increase from baseline > 30 msec will be flagged.

7.8 Prior and Concomitant Medications

Prior and concomitant medications recorded during the study will be coded with the World Health Organization (WHO) Drug Dictionary Version 01-Sep-2022_b3 and listed.

7.9 Physical Examination

A full physical examination will be performed at Screening. Symptom driven physical examinations will be performed pre-dose (within 24 hours prior to dosing) and Day 2 (Hour 23 in the CRF) of each period as well as Day 5 of Period 3. All data found in the CRF will be listed.

7.10 Columbia Suicide Severity Rating Scale

Columbia Suicide Severity Rating Scales will be assessed at Screening as well as Day -1, Day 2, and Day 5 of each period. All data found in the CRF will be listed.

8. SUMMARY OF CHANGES FROM PROTOCOL-PLANNED ANALYSIS

Screen failure data (demographics or reason for screen failure) will not be summarized though the protocol indicated that these would be summarized.

9. SUMMARY TABLES, FIGURES, AND LISTINGS

Summary tables and figures are numbered following the International Council on Harmonization (ICH) structure but may be renumbered as appropriate during the compilation of the tables and figures for the CSR. Note that summary tables and figures will be generated using SAS® Version 9.4 or higher as appropriate.

In-text tables and figures will be generated as RTF and all other tables and listings will be generated as SAS® LST format and converted to MS Word. In compliance Celerion SOP/PG, SAS® outputs will not be manually edited.

While not noted on the shells, source footnotes will be included to reference the data domains support the SAS output.

9.1 In-text Summary Tables and Figures

The following is a list of table and figure titles that will be included in the text of the CSR. Tables and figures will be numbered appropriately during compilation of the CSR.

Section 10:

Number	Title	Shell
Table 10-1	Disposition Summary (Safety Set)	IDS

Section 11:

Number	Title	Shell
Table 11-1	Demographic Summary (Safety Set)	IDEM
Table 11-2	Summary of Plasma CVN424 Pharmacokinetics Following Administration of 150 mg CVN424 Suspension-Fasted, Tablet-Fasted, and Tablet-Fed (Pharmacokinetic Set)	ITPPar1
Table 11-3	Summary of Statistical Comparisons of Plasma CVN424 Pharmacokinetic Parameters for 150 mg CVN424 Tablet-Fasted Versus Suspension-Fasted (Pharmacokinetic Set)	ITPStat1
Table 11-4	Summary of Statistical Comparisons of Plasma CVN424 Pharmacokinetic Parameters for 150 mg CVN424 Tablet-Fed Versus Suspension-Fasted (Pharmacokinetic Set)	ITPStat1

Number	Title	Shell
Table 11-5	Summary of Statistical Comparisons of Plasma CVN424 Pharmacokinetic Parameters for 150 mg CVN424 Tablet-Fed Versus Tablet-Fasted (Pharmacokinetic Set)	ITPStat1
Table 11-6	Summary of Nonparametric Statistical Comparison of Plasma CVN424 T_{max}, T_{lag}: Tablet-Fasted Versus Suspension-Fasted (Pharmacokinetic Set)	CPStat2/ITPStat2
Table 11-7	Summary of Nonparametric Statistical Comparison of Plasma CVN424 T_{max}, T_{lag}: Tablet-Fed Versus Suspension-Fasted (Pharmacokinetic Set)	CPStat2/ITPStat2
Table 11-8	Summary of Nonparametric Statistical Comparison of Plasma CVN424 T_{max}, T_{lag}: Tablet-Fed Versus Tablet-Fasted (Pharmacokinetic Set)	CPStat2/ITPStat2
Figure 11-1	Arithmetic Mean Plasma CVN424 Concentration Versus Time Profiles Following 150 mg CVN424 Suspension-Fasted, Tablet-Fasted and Tablet-Fed (Linear Scale) (Pharmacokinetic Set)	PFPConc2
Figure 11-2	CVN424 Box Plots for $AUC_{0\text{-}96h}$ by Treatment Following 150 mg CVN424 (Pharmacokinetic Set)	PFPBox1
Figure 11-3	CVN424 Box Plots for C_{max} by Treatment Following 150 mg CVN424 (Pharmacokinetic Set)	PFPBox1
Figure 11-4	CVN424 Box Plots for $AUC_{0\text{-}t}$ by Treatment Following 150 mg CVN424 (Pharmacokinetic Set)	PFPBox1

Section 12:

Number	Title	Shell
Table 12-1	Treatment-Emergent Adverse Event Frequency by Treatment - Number of Participants Reporting the Event (% of Participants Dosed) (Safety Set)	IAES

9.2 Section 14 Summary Tables and Figures

The following is a list of table and figure titles that will be included in Section 14 of the report. Table and figure titles may be renumbered as appropriate during the compilation of the report.

14.1 Demographic Data Summary Tables and Figures

Number	Title	Shell
Table 14.1.1	Disposition Summary (Safety Set)	CDS
Table 14.1.2	Participant Dosing Status and Study Disposition (Safety Set)	SDS
Table 14.1.3	Demographic Summary (Safety Set)	CDEM

14.2 Pharmacokinetic Data Summary Tables and Figures

14.2.1 Plasma CVN424 Tables

Number	Title	Shell
Table 14.2.1.1	Plasma CVN424 Concentrations (ng/mL) Following Administration of 150 mg CVN424 Suspension-Fasted (Pharmacokinetic Set)	CPCONC1
Table 14.2.1.2	Plasma CVN424 Concentrations (ng/mL) Following Administration of 150 mg CVN424 Tablet-Fasted (Pharmacokinetic Set)	CPCONC1
Table 14.2.1.3	Plasma CVN424 Concentrations (ng/mL) Following Administration of 150 mg CVN424 Tablet-Fed (Pharmacokinetic Set)	CPCONC1
Table 14.2.1.4	Plasma CVN424 Pharmacokinetic Parameters Following Administration of 150 mg CVN424 Suspension-Fasted (Pharmacokinetic Set)	CPPAR1
Table 14.2.1.5	Plasma CVN424 Pharmacokinetic Parameters Following Administration of 150 mg CVN424 Tablet-Fasted (Pharmacokinetic Set)	CPPAR1
Table 14.2.1.6	Plasma CVN424 Pharmacokinetic Parameters Following Administration of 150 mg CVN424 Tablet-Fed (Pharmacokinetic Set)	CPPAR1
Table 14.2.1.7	Plasma CVN424 Pharmacokinetic Parameter Ratios: Tablet-Fasted/Suspension-Fasted, Tablet-Fed/Tablet-Fasted, and Tablet-Fed/Suspension-Fasted (Pharmacokinetic Set)	CPR1
Table 14.2.1.8	Statistical Comparisons of Plasma CVN424 Pharmacokinetic Parameters: AUC0-t, AUC0-96h, and Cmax Tablet-Fasted Versus Suspension-Fasted (Pharmacokinetic Set)	CPStat1

Number	Title	Shell
Table 14.2.1.9	Statistical Comparisons of Plasma CVN424 Pharmacokinetic Parameters: AUC0-t, AUC0-96h, and Cmax Tablet-Fed Versus Suspension-Fasted (Pharmacokinetic Set)	CPStat1
Table 14.2.1.10	Statistical Comparisons of Plasma CVN424 Pharmacokinetic Parameters: AUC0-t, AUC0-96h, and Cmax Tablet-Fed Versus Tablet-Fasted (Pharmacokinetic Set)	CPStat1
Table 14.2.1.11	Nonparametric Statistical Comparison of Plasma CVN424 Tmax and Tlag: Tablet-Fasted Versus Suspension-Fasted (Pharmacokinetic Set)	CPStat2
Table 14.2.1.12	Nonparametric Statistical Comparison of Plasma CVN424 Tmax and Tlag: Tablet-Fed Versus Suspension-Fasted (Pharmacokinetic Set)	CPStat2
Table 14.2.1.13	Nonparametric Statistical Comparison of Plasma CVN424 Tmax and Tlag: Tablet-Fed Versus Tablet-Fasted (Pharmacokinetic Set)	CPStat2

14.2.2 Plasma CVN424 Figures

Number	Title	Shell
Figure 14.2.2.1	Arithmetic Mean (SD) Plasma CVN424 Concentration Versus Time Profiles Following Administration of 150 mg CVN424 Suspension-Fasted, Tablet-Fasted, and Tablet- Fed (Linear Scale) (Pharmacokinetic Set)	PFPConc1
Figure 14.2.2.2	Arithmetic Mean Plasma CVN424 Concentration Versus Time Profiles Following Administration of 150 mg CVN424 Suspension-Fasted, Tablet-Fasted, and Tablet- Fed (Linear Scale) (Pharmacokinetic Set)	PFPConc2
Figure 14.2.2.3	Arithmetic Mean Plasma CVN424 Concentration Versus Time Profiles Following Administration of 150 mg CVN424 Suspension-Fasted, Tablet-Fasted, and Tablet-Fed (Semi-Log Scale) (Pharmacokinetic Set)	PFPConc3
Figure 14.2.2.4	CVN424 Box Plots for AUC0-96h by Treatment Following 150 mg CVN424 (Pharmacokinetic Set)	Shell PFPBox1
Figure 14.2.2.5	CVN424 Box Plots for Cmax by Treatment Following 150 mg CVN424 (Pharmacokinetic Set)	Shell PFPBox1

Number	Title	Shell
Figure 14.2.2.6	CVN424 Box Plots for AUC0-t by Treatment Following 150 mg CVN424 (Pharmacokinetic Set)	Shell PFPBox1

14.2.3 Urine CVN424 Tables

Number	Title	Shell
Table 14.2.3.1	Urinary Excretion of CVN424 Following Administration of 150 mg CVN424 Tablet-Fasted (Pharmacokinetic Set)	C(A)UPar3

14.2.4 Urine CVN424 Figures

Number	Title	Shell
Figure 14.2.4.1	Arithmetic Mean (SD) Cumulative Amount of CVN424 Excreted in Urine Following Administration of 150 mg CVN424 Tablet-Fasted (Linear Scale) (Pharmacokinetic Set)	PFPConc1
Figure 14.2.4.2	Arithmetic Mean Cumulative Amount of CVN424 Excreted in Urine Following Administration of 150 mg CVN424 Tablet-Fasted (Linear Scale) (Pharmacokinetic Set)	PFPConc2

14.3 Safety Data Summary Tables

14.3.1 Displays of Adverse Events

Number	Title	Shell
Table 14.3.1.1	Treatment-Emergent Adverse Event Frequency by Treatment – Number of Participants Reporting the Event (% of Participants Dosed) (Safety Set)	CAES
Table 14.3.1.2	Treatment-Emergent Adverse Event Frequency by Treatment – Number of Adverse Events (% of Total Adverse Events) (Safety Set)	CAEF
Table 14.3.1.3	Treatment-Emergent Adverse Event Frequency by Treatment, Severity, and Relationship to Study Product – Number of Adverse Events (Safety Set)	CAESR

14.3.2 Listings of Deaths, other Serious and Significant Adverse Events

Number	Title	Shell
Table 14.3.2.1	Serious Adverse Events (Safety Set)	16.2.7

14.3.3 Narratives of Deaths, other Serious and Certain other Significant Adverse Events

14.3.4 Abnormal Laboratory Value Listing (each participant)

Number	Title	Shell
Table 14.3.4.1	Out-of-Range Values and Recheck Results – Serum Chemistry (Safety Set)	CLBO
Table 14.3.4.2	Out-of-Range Values and Recheck Results – Hematology (Safety Set)	
Table 14.3.4.3	Out-of-Range Values and Recheck Results – Coagulation (Safety Set)	
Table 14.3.4.4	Out-of-Range Values and Recheck Results – Urinalysis (Safety Set)	

14.3.5 Displays of Other Laboratory, Vital Signs, Electrocardiogram, Physical Examination, and Other Safety Data

Number	Title	Shell
Table 14.3.5.1	Clinical Laboratory Summary and Change From Baseline – Serum Chemistry (Safety Set)	CLBD
Table 14.3.5.2	Clinical Laboratory Shift From Baseline – Serum Chemistry (Safety Set)	CLBS
Table 14.3.5.3	Clinical Laboratory Summary and Change From Baseline – Hematology (Safety Set)	CLBD
Table 14.3.5.4	Clinical Laboratory Shift From Baseline – Hematology (Safety Set)	CLBS
Table 14.3.5.5	Clinical Laboratory Summary and Change From Baseline – Coagulation (Safety Set)	CLBD
Table 14.3.5.6	Clinical Laboratory Shift From Baseline – Coagulation (Safety Set)	CLBS
Table 14.3.5.7	Clinical Laboratory Summary and Change From Baseline – Urinalysis (Safety Set)	CLBD

Number	Title	Shell
Table 14.3.5.8	Clinical Laboratory Shift From Baseline – Urinalysis (Safety Set)	CLBS
Table 14.3.5.9	Vital Sign Summary and Change From Baseline (Safety Set)	CVS
Table 14.3.5.10	12-Lead Electrocardiogram Summary and Change From Baseline (Safety Set)	CEG
Table 14.3.5.11	12-Lead Electrocardiogram – Categorical Summary (Safety Set)	CEGC

9.3 Section 16 Data Listings

Note: Hepatitis and HIV results will be provided by the clinical laboratory, presented in the by-participant data listings, and included in the database transfer. All data will be presented as outlined in the CRF (i.e., time point information will be consistent with the CRF data).

Data listings are numbered following the ICH structure but may be renumbered as appropriate during the compilation of the TFLs for the CSR. The following is a list of appendix numbers and titles that will be included as data listings:

16.1 Study Information

16.1.9 Statistical Methods

Number	Title
Appendix 16.1.9.1	Statistical Analysis Plan
Appendix 16.1.9.2	Statistical Methods – Pharmacokinetics

16.1.10 Clinical Laboratory Reference Ranges

Number	Title
Appendix 16.1.10.1	Clinical Laboratory Reference Ranges

16.2 Participant Data Listings

16.2.1 Participant Discontinuation

Number	Title
Appendix 16.2.1.1	Participant Disposition (Safety Set)
Appendix 16.2.1.2	Participant Disposition for Screen Failures

16.2.2 Protocol Deviations

Number	Title
Appendix 16.2.2.1	Protocol Deviations

16.2.3 Participants Excluded From the Pharmacokinetic Analysis

Number	Title
Appendix 16.2.3.1	Participants Excluded From the Pharmacokinetic Analysis

Note: Appendices 16.2.2 and 16.2.3 are generated in MS Word for inclusion in the study report.

16.2.4 Demographic Data

Number	Title
Appendix 16.2.4.1	Demographics (Safety Set)
Appendix 16.2.4.2	Demographics for Screen Failures
Appendix 16.2.4.3	Physical Examination (Part I of II) (Safety Set)
Appendix 16.2.4.4	Physical Examination (Part II of II) (Safety Set)
Appendix 16.2.4.5	Physical Examination Descriptions (Safety Set)
Appendix 16.2.4.6	Medical History (Safety Set)
Appendix 16.2.4.7	Substance Use (Safety Set

16.2.5 Compliance and/or Drug Concentration Data

Number	Title
Appendix 16.2.5.1	Participant Eligibility (Safety Set)
Appendix 16.2.5.2	Participant Eligibility for Screen Failures
Appendix 16.2.5.3	Test Compound Description
Appendix 16.2.5.4	Test Compound Administration Times (Safety Set)
Appendix 16.2.5.5	Meal Times (Safety Set)
Appendix 16.2.5.6	Prior and Concomitant Medications (Safety Set)
Appendix 16.2.5.7	Pharmacokinetic Blood Draw Times and Concentration Data (Safety Set)
Appendix 16.2.5.8	Pharmacokinetic Urine Data (Safety Set)

16.2.6 Individual Pharmacokinetic Data

Number	Title	Shell
Appendix 16.2.6.1	Individual Plasma CVN424 Concentration Versus Time Profiles for <Participant #>(Linear and Semi-Log Scale)	PFPConc5
Appendix 16.2.6.2	Cumulative Amount CVN424 Excreted in Urine Versus End of Collection Interval (Linear Scale) for <Participant #>	PFPConc5
Appendix 16.2.6.3	Intervals (Hours) Used for Determination of Plasma CVN424 Kel Values (Pharmacokinetic Set)	CPKel1

16.2.7 Adverse Events Listings

Number	Title
Appendix 16.2.7.1	Adverse Events (Safety Set)
Appendix 16.2.7.2	Details for Serious Adverse Events (Safety Set) *This listing will be removed if no serious adverse events are reported in the safety population.*
Appendix 16.2.7.3	Adverse Events for Screen Failures
Appendix 16.2.7.4	Details for Serious Adverse Events for Screen Failures *This listing will be removed if no events meet this criteria*

16.2.8 Clinical Laboratory Reports

Number	Title
Appendix 16.2.8.1	Clinical Laboratory Report - Serum Chemistry (Safety Set)
Appendix 16.2.8.2	Clinical Laboratory Report - Hematology (Safety Set)
Appendix 16.2.8.3	Clinical Laboratory Report - Coagulation (Safety Set)
Appendix 16.2.8.4	Clinical Laboratory Report - Urinalysis (Safety Set)
Appendix 16.2.8.5	Clinical Laboratory Report - Urine Drug Screening (Safety Set)
Appendix 16.2.8.6	Clinical Laboratory Report - Virology (Safety Set)
Appendix 16.2.8.7	Vital Signs (Safety Set)
Appendix 16.2.8.8	Orthostatic Vital Signs (Safety Set)
Appendix 16.2.8.9	12-Lead Electrocardiogram (Safety Set)

Number	Title
Appendix 16.2.8.10	12-Lead Electrocardiogram – Averages of Triplicates (Safety Set)
Appendix 16.2.8.11	Columbia-Suicide Severity Rating Scale (C-SSRS) Questions – Baseline/Screening
Appendix 16.2.8.12	Columbia-Suicide Severity Rating Scale (C-SSRS) Responses – Baseline/Screening (Safety Set)
Appendix 16.2.8.13	Columbia-Suicide Severity Rating Scale (C-SSRS) Questions – Since Last Visit
Appendix 16.2.8.14	Columbia-Suicide Severity Rating Scale (C-SSRS) Responses – Since Last Visit (Safety Set)

10. TABLE, FIGURE, AND LISTING SHELLS

The following table shells provide a framework for the display of data from this study. The shells may change due to unforeseen circumstances. These shells may not be reflective of every aspect of this study, but are intended to show the general layout of the tables that will be presented and included in the final report. Unless otherwise noted, all in-text tables will be presented in Times New Roman font size 9 and post-text tables will be presented in Courier New font size 9. In-text tables and figures will be generated as RTF and all other tables and listings will be generated as SAS® LST format and converted to MS Word. In compliance Celerion SOP/PG, SAS® outputs will not be manually edited.

While not noted on the shells, source footnotes will be included to reference the data domains support the SAS output.

10.1 In-text Summary Tables Shells

In-text tables will be in the following RFT format:

Table IDS Disposition Summary (Safety Set)

	Randomized Treatment Sequence						
Category	**ABC**	**BCA**	**CAB**	**ACB**	**BAC**	**CBA**	**Overall**
Dosed	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Completed Study	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Discontinued From Study	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
<Reason>	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Completed Treatment	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Discontinued From Treatment	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
<Reason>	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)

Treatment A: < >
Treatment B: < >
Treatment C: < >

Source: Table 14.1.1
Program: /CAXXXXX/sas_prg/stsas/intext/t_disp.sas DDMMMYYYY HH:MM

Table IDEM Demographic Summary (Safety Set)

		Randomized Treatment Sequence						
Trait	**Category/Statistic**	**ABC**	**BCA**	**CAB**	**ACB**	**BAC**	**CBA**	**Overall**
Sex	Female	XX (XX%)	XX (XX%)	Similar to previous columns				XX (XX%)
	Male	XX (XX%)	XX (XX%)					XX (XX%)
Race	Asian	XX (XX%)	XX (XX%)					XX (XX%)
	Black or African American	XX (XX%)	XX (XX%)					XX (XX%)
	White	XX (XX%)	XX (XX%)					XX (XX%)
Ethnicity	Hispanic or Latino	XX (XX%)	XX (XX%)					XX (XX%)
	Not Hispanic or Latino	XX (XX%)	XX (XX%)					XX (XX%)
Age (yr)	n	X	X					X
	Mean	X.X	X.X					X.X
	SD	X.XX	X.XX					X.XX
	Minimum	XX	XX					XX
	Median	X.X	X.X					X.X
	Maximum	XX	XX					XX
Body Mass Index (kg/m^2)	n	X	X					X
	Mean	X.X	X.X					X.X
	SD	X.XX	X.XX					X.XX
	Minimum	XX	XX					XX
	Median	X.X	X.X					X.X
	Maximum	XX	XX					XX
Height (cm)	n	X	X					X
	Mean	X.X	X.X					X.X
	SD	X.XX	X.XX					X.XX
	Minimum	XX	XX					XX
	Median	X.X	X.X					X.X
	Maximum	XX	XX					XX
Weight (kg)	n	X	X					X
	Mean	X.X	X.X					X.X
	SD	X.XX	X.XX					X.XX

		Randomized Treatment Sequence						
Trait	**Category/Statistic**	**ABC**	**BCA**	**CAB**	**ACB**	**BAC**	**CBA**	**Overall**
	Minimum	XX	XX					XX
	Median	X.X	X.X					X.X
	Maximum	XX	XX					XX

Treatment A: < >
Treatment B: < >
Treatment C: < >
Descriptive statistics for body mass index, height, and weight are calculated using Screening measurements.

Source: Table 14.1.3
Program: /CAXXXXX/sas_prg/stsas/intext/t_dem.sas DDMMMYYYY HH:MM

Table ITPPar1 Summary of Plasma CVN424 Pharmacokinetics Following Administration of 150 mg CVN424 Suspension-Fasted, Tablet-Fasted and Tablet-Fed (Pharmacokinetic Set)

Pharmacokinetic Parameters	Treatment <Y>	Treatment <X>
Param1 (units)	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]
Param2 (units)	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]
Param3 (units)	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]
Param4 (units)	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]
Treatment <Y>: <Label for Second Treatment> Treatment <X>: <Label for First Treatment> AUCs and C_{max} values are presented as geometric mean and geometric CV%. T_{max} and T_{lag} values are presented as median (minimum, maximum). Other parameters are presented as arithmetic mean (± SD). Source: Tables <XXXX> and <YYYY>		

Notes for Generating the Actual Table:

Treatments for column headers:

- Suspension-Fasted
- Tablet-Fasted
- Tablet-Fed

Presentation of Data:

- The following PK parameters will be presented in the following order: $AUC_{0\text{-}t}$, $AUC_{0\text{-}96h}$, $AUC_{0\text{-}inf}$, $AUC_{\%extrap}$, C_{max}, T_{lag}, T_{max}, K_{el}, $t½$, CL/F, and V_z/F.
- n will be presented as an integer (with no decimal);
- Summary statistics will be presented with same precision as defined in post-text shells

Programmer Note:

- Please use ITPar1 internal template
- For Table 11-2 the source tables will be 14.2.1.4 through 14.2.1.6.
- Indicate the Study "Treatment" in the column header as Suspension-Fasted, Tablet-Fasted, Tablet-Fed.
- Data for all 3 treatments will be presented on the same table.

Program: /CAXXXXX/sas_prg/pksas/intext-pk-tables.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_intext_pkparam.sas DDMMMYYYY HH:MM

Table ITPStat1 Summary of Statistical Comparisons of Plasma CVN424 Pharmacokinetic Parameters for 150 mg CVN424 Tablet-Fasted Versus Suspension-Fasted (Pharmacokinetic Set)

Parameter	Treatment <B> (Test)		Treatment <A> (Reference)		GMR (%)	90% Confidence Interval	Intra-subject CV%
	Geometric LSMs	n	Geometric LSMs	n			
param1 (units)	XXX.X	XX	XXX.X	XX	XX.XX	XX.XX - XX.XX	X.XX
param2 (units)	XXX.X	XX	XXX.X	XX	XX.XX	XX.XX - XX.XX	X.XX
param3 (units)	XXX.X	XX	XXX.X	XX	XX.XX	XX.XX - XX.XX	X.XX

Treatment <B>: <Label for Test Treatment>
Treatment <A>: <Label for Reference Treatment>
Geometric least-squares means (LSMs) are calculated by exponentiating the LSMs derived from the ANOVA.
Geometric Mean Ratio (GMR) = 100*(test/reference)
Intra-subject CV% was calculated as 100 x square root(exp[MSE]-1), where MSE = Residual variance from ANOVA.
Source: Table 14.2.1.8

Notes for Generating the Actual Table:

Calculations will use source data in all statistical analysist of PK parameter without prior rounding

Presentation of Data:

- The following PK parameters will be presented in the following order and with following units: AUC_{0-t} (ng*hr/mL), AUC_{0-96h} (ng*hr/mL), and C_{max} (ng/mL).
- If AUC_{0-t} equals AUC_{0-96h}, then only AUC_{0-96h} will be presented.
- n will be presented as an integer (with no decimal);
- _Geometric LSM will be presented with 3 significant figures. While, Geometric Mean Ratio, 90% CI and intra-subject CV% will be presented to 2 decimal places.
- Treatment columns will use the short description presented in Section 5 of the SAP.

Source tables will be:

- For Table 11-3, the source table will be 14.2.1.8. Tablet-Fasted is test and Suspension-Fasted is reference.
- For Tables 11-4, the source table will be 14.2.1.9. Tablet-Fed is test and Suspension-Fasted is reference.
- For Tables 11-5, the source table will be 14.2.1.10. Tablet-Fed is test and Tablet-Fasted is reference.

Program: /CAXXXXX/sas_prg/pksas/intext-pk-tables.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_intext_pkparam.sas DDMMMYYYY HH:MM

In-text Shell CPStat2/ITPStat2 will be in the following RFT format:

Table CPStat2/ITPStat2 Summary of Nonparametric Statistical Comparison of Plasma CVN424 T_{max} and T_{lag}: Tablet-Fasted Versus Suspension-Fasted (Pharmacokinetic Set)

	———Difference Tablet-Fasted–Suspension-Fasted———		
Parameter	Median	90% Confidence Interval	p-value
T_{max}	XXX	-XXXXX-XXXXX	XXXXX
T_{lg}	XXX	-XXXXX-XXXXX	XXXXX

Notes for Generating the Actual Table:

- All statistics will be presented with same precision as defined in post-text shells
- The 90% confidence interval is constructed using Wilcoxon Singed rank test.

Programmer Note:
- For Table 11-6 the source tables will be 14.2.1.11.
- For Table 11-7 the source tables will be 14.2.2.12.
- For Table 11-8 the source tables will be 14.2.2.13.

Program: /CAXXXXX/sas_prg/pksas/adam_programname.sas DDMMMYYYY HH:MM

Table IAES Treatment-Emergent Adverse Event Frequency by Treatment- Number of Participants Reporting the Event (% of Participants Dosed) (Safety Set)

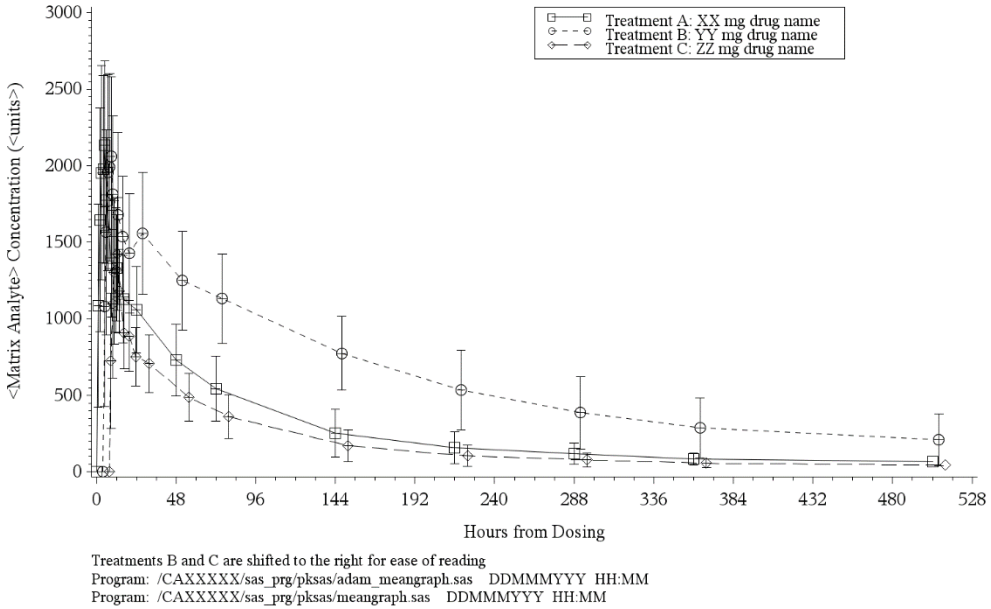
	Treatment			
Adverse Event	**A (N = X)**	**B (N = X)**	**C (N = X)**	**Overall (N = X)**
Number of Participants With TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Number of Participants Without TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Eye disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Visual blurred	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Gastrointestinal disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Dyspepsia	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Nausea	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal and connective tissue disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Back pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Muscle cramps	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)

Treatment A: < >
Treatment B: < >
Treatment C: < >.
Although a participant may have had 2 or more adverse events, the participant is counted only once within a category. The same participant may appear in different categories.
Adverse events are classified according to MedDRA Version 25.1.
TEAEs = Treatment-emergent adverse events

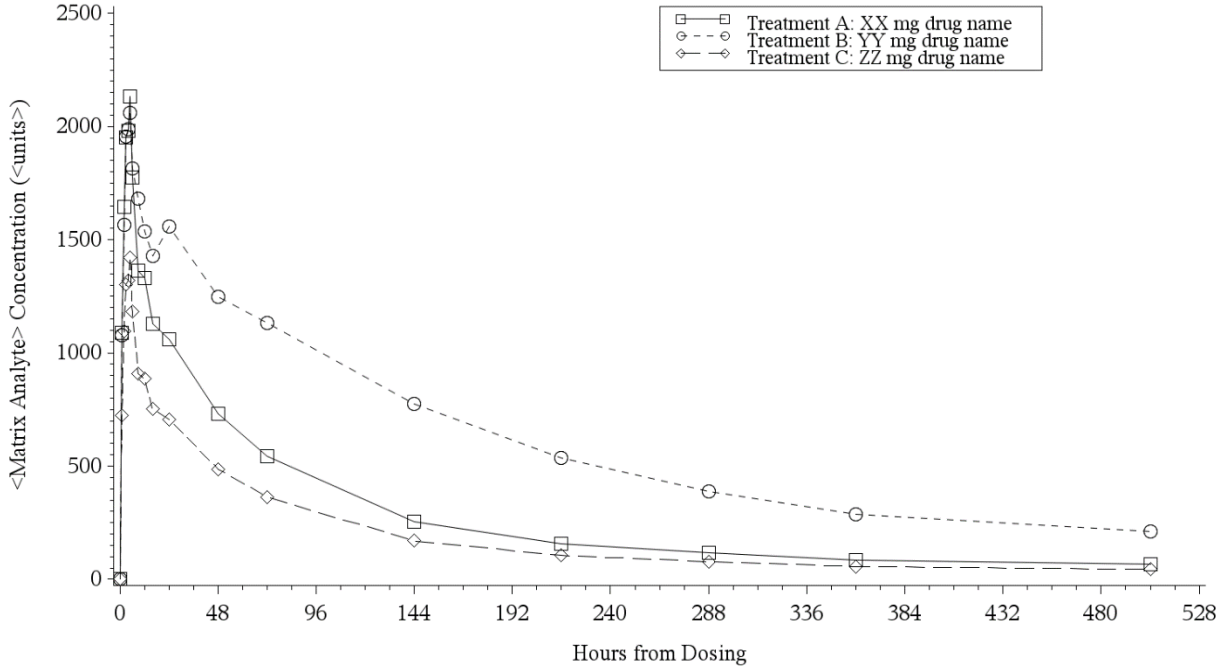
Source: Table 14.3.1.1
Program: /CAXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMMYYYY HH:MM

10.2 Figures Shells

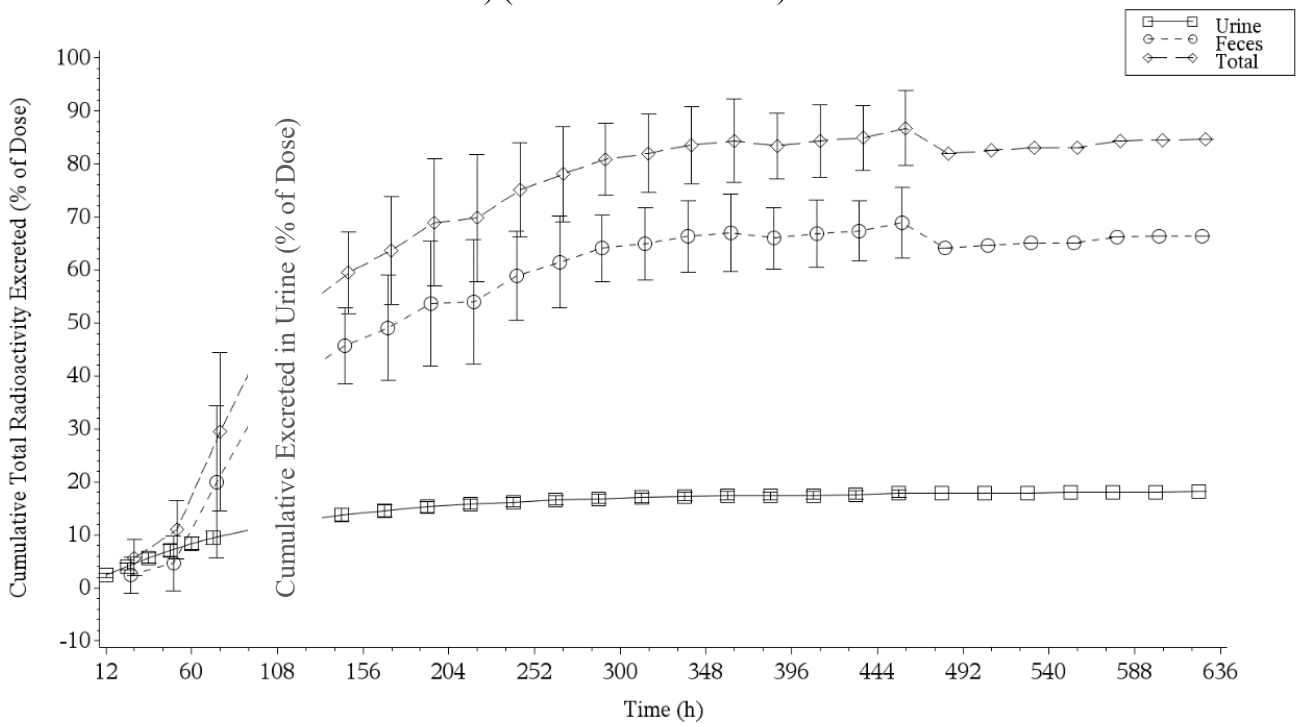
PFPConc1 Arithmetic Mean (SD) Plasma CVN424 Concentration Versus Time Profiles Following Administration of 150 mg CVN424 Suspension-Fasted, Tablet-Fasted, and Tablet-Fed (Linear Scale) (Pharmacokinetic Set)



PFPConc2 (For Plasma Matrix) Arithmetic Mean Plasma CVN424 Concentration Versus Time Profiles Following Administration of 150 mg CVN424 Suspension-Fasted, Tablet-Fasted, and Tablet-Fed (Linear Scale) (Pharmacokinetic Set)

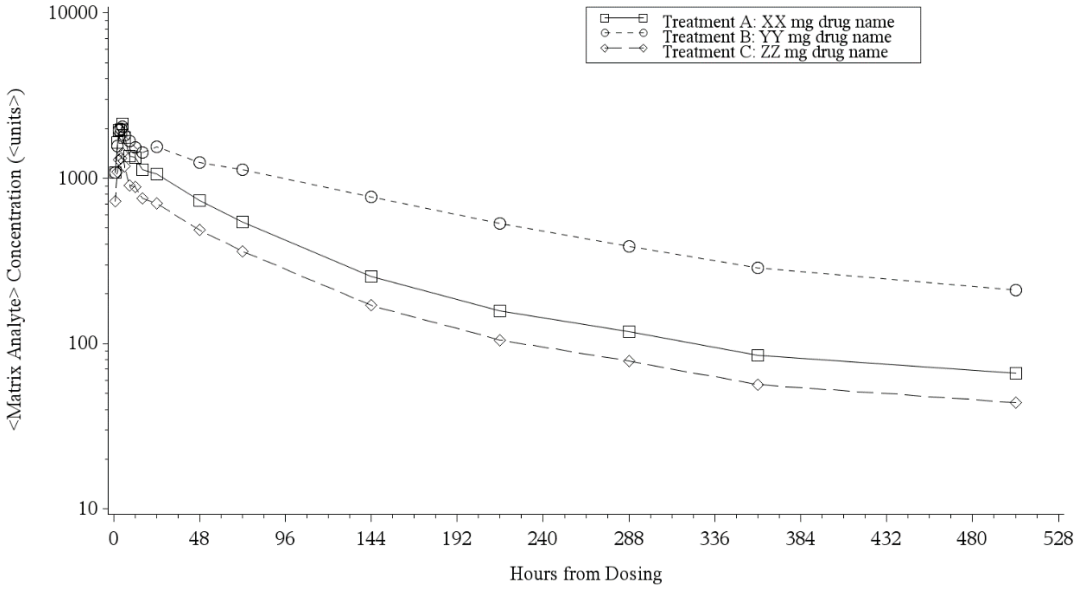


PFPConc2 (For Urine Matrix) Arithmetic Mean (SD) Cumulative Amount of CVN424 Excreted in Urine Following Administration of 150 mg CVN424 Tablet-Fasted (Linear Scale) (Pharmacokinetic Set)



Arithmetic mean cumulative amounts in urine will also be presented without SD error bars on the linear scale. Only Urine will be presented.

PFPConc3 Mean Plasma CVN424 Concentration Versus Time Profiles Following Administration of 150 mg CVN424 Suspension-Fasted, Tablet-Fasted, and Tablet- Fed (Semi-Log Scale) (Pharmacokinetic Set)



Program: /CAXXXXX/sas_prg/pksas/adam_meangraph.sas DDMMMYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/meangraph.sas DDMMMYYY HH:MM

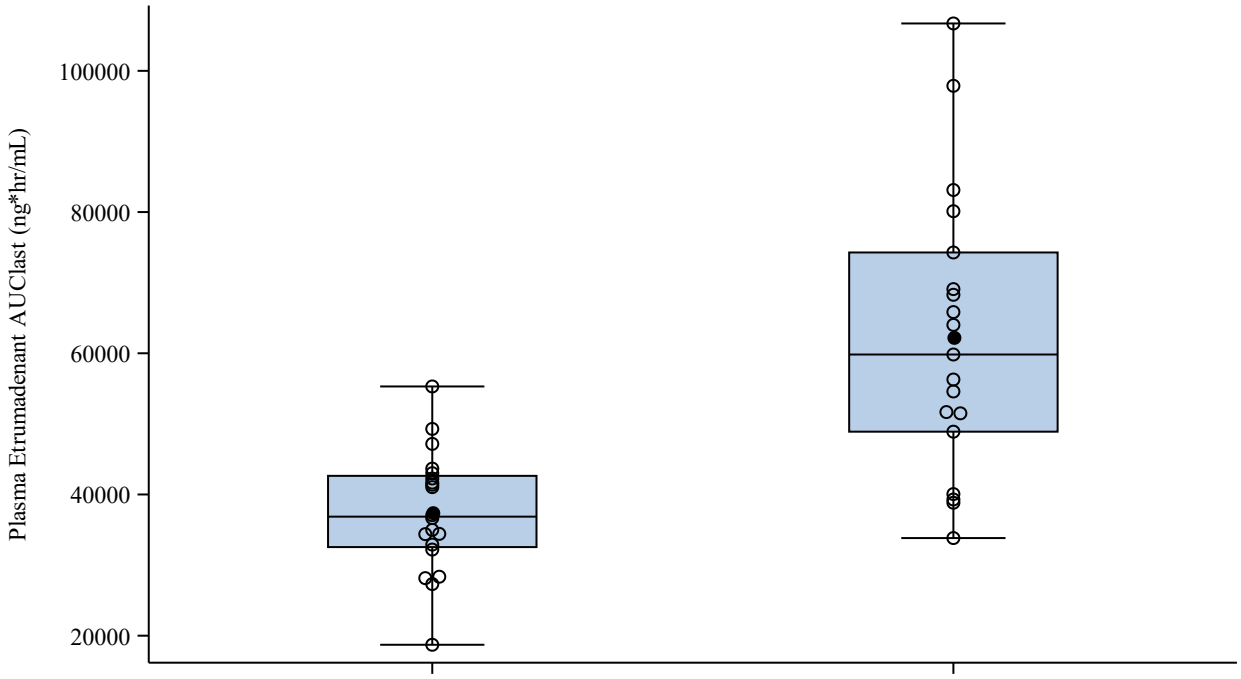
Notes for Generating the Actual Mean Figure:

Programmer's note:

- Legend labels for Figures 14.2.2.1, 14.2.2.2, and 14.2.2.3 are "Suspension-Fasted", "Tablet-Fasted", "Tablet-Fed".
- Y axis label will be <Matrix> <Analyte> Concentration (<unit>.
- X axis label will be "Time Postdose (hr)".
- Mean plots will have the 3 treatments overlaid.
- Add the footnote: <Treatment X and Y> are shifted to the right for ease of reading for figures with SD.

Program: /CAXXXXX/sas_prg/pksas/meangraph.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_meangraph.sas DDMMMYYYY HH:MM

PFPBox 1 CVN424 Box Plots for AUC0-t by Treatment Following 150 mg CVN424 (Pharmacokinetic Set)



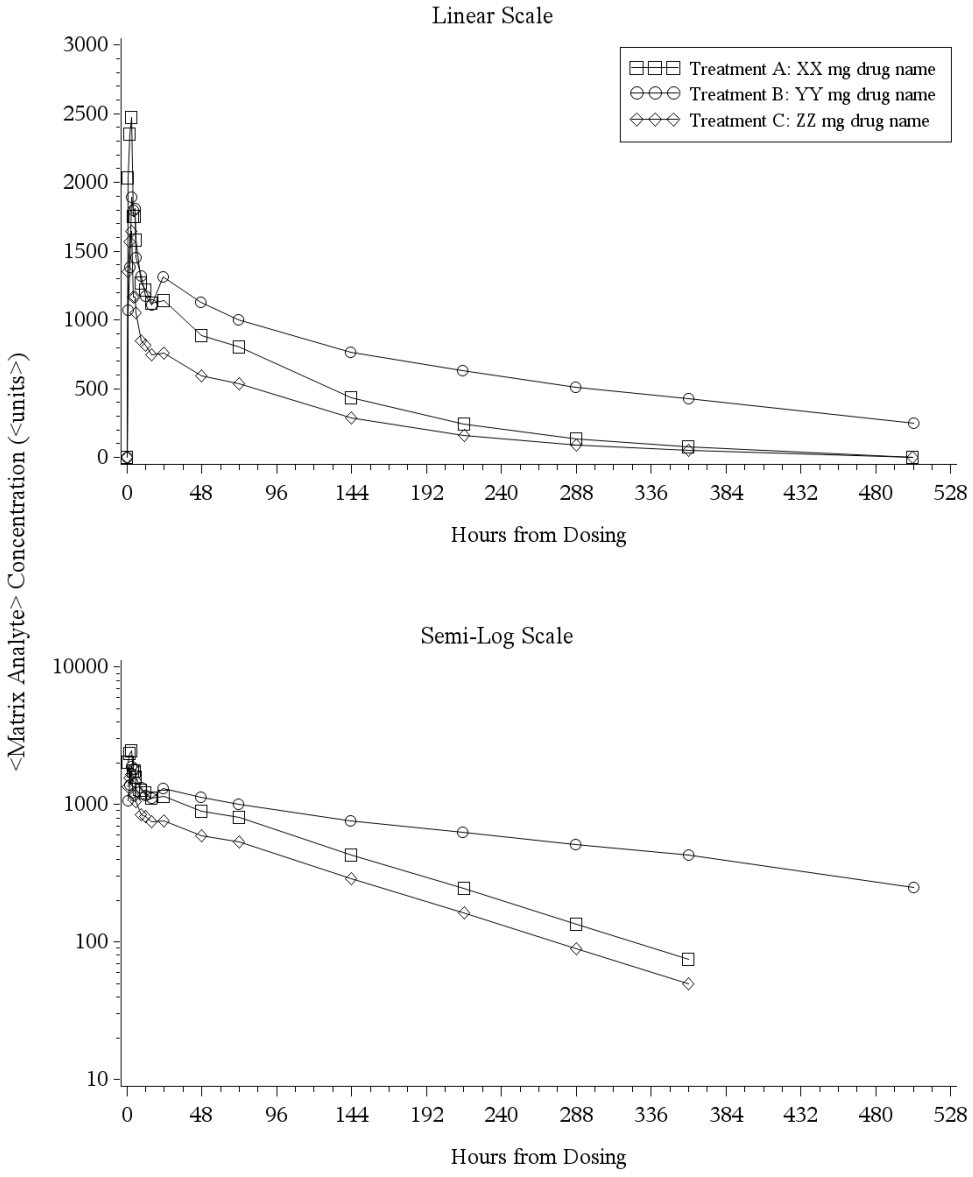
Notes for Generating the Actual Box Plot Figure:

Programmer's note:

- All 3 treatments will be displayed on the x-axis.
- X-axis labels will be "Suspension-Fasted", "Tablet-Fasted", "Tablet-Fed".
- Y axis label will be <PK parameter> (<unit>).
- If AUC0-t equals AUC0-96h, then only box plot of AUC0-96h will be presented.
- Box plots will have individual data points overlaid (see any outliers). Box plots will have the following: solid line will represent the mean, dotted line the median, lower and upper lower delimitations of the box represent the 25th and 75th quartiles, whiskers are 1.5-times the inter-quartile range (IQR) and the small markers represent, if any, the data points beyond the IQR whiskers.

Appendix PFPConc5

Individual Plasma CVN424 Concentration Versus Time Profiles for <Participant #> (Linear and Semi-Log Scale)



Program: /CAXXXXX/sas_prg/pksas/adam_indgraph.sas DDMMMYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/indgraph-all.sas DDMMMYYY HH:MM

Notes for Generating the Actual Individual Figures:

- Legends will be
  "<Short treatment description> Treatment <X>" eg Suspension-Fasted, Tablet-Fasted, Tablet-Fed.
- Y-axis label will be "Plasma CVN424 Concentration (ng/mL)" appropriate
- X-axis label will be "Hours From Dosing"

Note for programmer:

- For urine matrix with sampling interval, only linear plot will be displayed.

10.3 Section 14 Summary Tables Shells

Tables will be in the following LST format.

Table CDS Disposition Summary (Safety Set)

	Randomized Treatment Sequence						
Category	ABC	BCA	CAB	ACB	BAC	CBA	Overall
Dosed	XX (XXX%)	XX (XXX%)	XX (XXX%)	<similar to previous columns>			
Completed Study	XX (XX%)	XX (XX%)	XX (XX%)				
Discontinued From Study	X (XX%)	X (XX%)	X (XX%)				
<Reason>	X (XX%)	X (XX%)	X (XX%)				
Completed Treatment	XX (XX%)	XX (XX%)	XX (XX%)				
Discontinued From Treatment	X (XX%)	X (XX%)	X (XX%)				
<Reason>	X (XX%)	X (XX%)	X (XX%)				

Treatment A: a single oral dose of 150 mg CVN424 suspension under fasted condition
Treatment B: a single oral dose of 150 mg CVN424 tablet under fasted condition
Treatment C: a single oral dose of 150 mg CVN424 tablet under fed condition

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1programname2022Q1.sas DDMMMYYYY HH:MM

Table SDS Participant Dosing Status and Study Disposition (Safety Set)

Participant Number	Randomized Treatment Sequence	Dosed			Study Completion	
		A	B	C	Status	Date
X	ABC	Yes	No	No	Discontinued From Study: <Reason>	DDMONYYYY
X	ABC	Yes	Yes	Yes	Completed Study	DDMONYYYY
X	ABC	Yes	Yes	Yes	Completed Study	DDMONYYYY
X	ABC	Yes	Yes	Yes	Completed Study	DDMONYYYY
<similar for all participants and all sequences>						
		XX	XX	XX		

Programmer Note: Please refer to Section 5 for the treatment description.

Treatment A: < >
Treatment B: < >
Treatment C: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CDEM Demographic Summary (Safety Set)

		Randomized Treatment Sequence						
Trait	Category/Statistic	ABC	BCA	CAB	ACB	BAC	CBA	Overall
Sex	Male	X (XX%)	X (XX%)	X (XX%)	<similar to previous columns>			
	Female	X (XX%)	X (XX%)	X (XX%)				
Race	Asian	X (XX%)	X (XX%)	X (XX%)				
	Black or African American	X (XX%)	X (XX%)	X (XX%)				
	White	X (XX%)	X (XX%)	X (XX%)				
Ethnicity	Hispanic or Latino	X (XX%)	X (XX%)	X (XX%)				
	Not Hispanic or Latino	X (XX%)	X (XX%)	X (XX%)				
Age (yr)	n	X	X	X				
	Mean	X.X	X.X	X.X				
	SD	X.XX	X.XX	X.XX				
	Minimum	XX	XX	XX				
	Median	X.X	X.X	X.X				
	Maximum	XX	XX	XX				

Treatment A: < >
Treatment B: < >
Treatment C: < >
Descriptive statistics for body mass index, height, and weight are calculated using screening measurements.

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Programmer Note: Please include BMI, Height, and Weight

Table CPCCONC1 Plasma CVN424 Concentrations (ng/mL) Following Administration of 150 mg CVN424 Suspension-Fasted (Pharmacokinetic Set)

Subject Number	Treatment Sequence	Study Period	Sample Times (hr) Predose	XX	XX	XX	XX	XX	XX	XX	XX
X	XXX	X	BLQ	XX	XX	XX	XX	XX	XX	XX	XX
X	XXX	X	BLQ	XX	XX	XX	XX	XX	XX	XX	XX
X	XXX	X	BLQ	XX	XX	XX	XX	XX	XX	XX	XX
n			XX	XX	XX	XX	XX	XX	XX	XX	XX
Mean			XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD			XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
CV%			.	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SEM			XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum			XX	XX	XX	XX	XX	XX	XX	XX	XX
Median			XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum			XX	XX	XX	XX	XX	XX	XX	XX	XX

For the calculation of summary statistics, values that are below the limit of quantitation (BLQ) of <XX> are treated as 0 before the first quantifiable concentration and as missing elsewhere.
. = Value missing or not reportable.

Notes for Generating the Actual Table:

Presentation of Data:
Concentrations will be presented to same precision as in bio data.
Summary statistics presentation with respect to the precision of the bio data: n = integer; Mean and Median +1; SD and SEM +2, Min and Max +0, CV% to 1 decimal

Programmer Note:
PK Time points are from Protocol: Predose (within 15 minutes prior to dosing; 60 minutes for the fed treatment), 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, 48, 60, 72, 84 and 96h postdose.

Program: /CAXXXXX/sas_prg/pksas/adam_conc.sas DDMMMYYYY HH:MM

Table CPPar1 Plasma CVN424 Pharmacokinetic Parameters Following Administration of 150 mg CVN424 Suspension-Fasted (Pharmacokinetic Set)

			Parameters					
Paticipant Number	Treatment Sequence	Study Period	param1 (units)	param2 (units)	param3 (units)	param4 (units)	param5 (units)	param6 (units)
X	XXX	X	XXX	X.XX	XXX	XXX	XX.X	X.XXX
X	XXX	X	XX.X	X.XX	XXX	XXX	XX.X	X.XXX
X	XXX	X	XXX	X.XX	XXX	XXX	XX.X	X.XXX
X	XXX	X	XX.X	X.XX	XXX	XXX	XX.X	X.XXX
X	XXX	X	XX.X	X.XX	XXX	XXX	XX.X	X.XXX
X	XXX	X	X.XX	X.XX	XXX	XXX	XX.X	X.XXX
X	XXX	X	XXX	X.XX	XXX	XXX	XX.X	X.XXX
n			XX	XX	XX	XX	XX	XX
Mean			XXX.X	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
SD			XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
CV%			XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SEM			XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum			XX.X	X.XX	XXX	XXX	XX.X	X.XXX
Median			XX.XX	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
Maximum			XXX	X.XX	XXX	XXX	XX.X	X.XXX
Geom Mean			XXX.X	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
Geom CV%			XX.X	XX.X	XX.X	XX.X	XX.X	XX.X

. = Value missing or not reportable.

Notes for Generating the Actual Table:

Presentation of Data:

- PK Parameters will be presented in the following order and with following units: AUC0-t (ng*hr/mL), AUC0-96h (ng*hr/mL), AUC0-inf (ng*hr/mL), AUC%extra(%), Cmax (ng/mL), Tlag (hr), Tmax (hr), Kel (1/hr), t½ (hr), CL/F (L/hr), Vz/F (L). n will be presented as an integer (with no decimal);
- Parameter values for exposure based parameters (i.e. AUCs, Cmax, Vz/F, CL/F) will be presented with, at maximum, the precision of the bio data, and, at minimum, 3 significant figures. Summary statistics for exposure parameters will be presented as: Mean, Median, and Geom Mean+1; SD and SEM +2, Min and Max +0.

- Values for time-based parameters (i.e. Tmax, Tlag, t1/2) will be presented with 2 decimals. Summary statistics for time-based parameters will be presented as: Mean, Median, and Geom Mean +1; SD +2, Min and Max +0.
- Values for rate constants (i.e. Kel) will be presented with 3 significant figures. Summary statistics for Kel will be presented as: Mean, Median, and Geom Mean +1; SD and SEM +2, Min and Max +0.
- CV% and Geom CV% for all parameters will be presented with 1 decimal

```
Program:  /CAXXXXX/sas_prg/pksas/pk-tables.sas        DDMMMYYYY  HH:MM
Program:  /CAXXXXX/sas_prg/pksas/adam_pkparam.sas     DDMMMYYYY  HH:MM
```

Table CPR1. Plasma CVN424 Pharmacokinetic Parameter Ratios: Tablet-Fasted/Suspension-Fasted and Tablet-Fed/Tablet-Fasted (Pharmacokinetic Set)

Subject Number	Treatment Sequence	param 1						param 2					
		X (units)	Y (units)	Z (units)	Ratio Y/X (%)	Ratio Z/Y (%)	Ratio Z/X (%)	X (units)	Y (units)	Z (units)	Ratio Y/X (%)	Ratio Z/Y (%)	Ratio Z/X (%)
X	XXX	X	X	X	X.XX	X.XX	X.XX	X	X	X	X.XX	X.XX	X.XX
X	XXX	X	X	X	X.XX	X.XX	X.XX	X	X	X	X.XX	X.XX	X.XX
X	XXX	X	X	X	X.XX	X.XX	X.XX	X	X	X	X.XX	X.XX	X.XX
X	XXX	X	X	X	X.XX	X.XX	X.XX	X	X	X	X.XX	X.XX	X.XX
n		X	X	X	X	X	X	X	X	X	X	X	X
Mean		X	X	X	X.XX	X.XX	X.XX	X	X	X	X.XX	X.XX	X.XX
Geom Mean		X	X	X	X.XX	X.XX	X.XX	X	X	X	X.XX	X.XX	X.XX
SD		X	X	X	X.XX	X.XX	X.XX	X	X	X	X.XX	X.XX	X.XX
CV%		X	X	X	X.X	X.X	X.X	X	X	X	X.X	X.X	X.X
Geom CV%		X	X	X	X.X	X.X	X.X	X	X	X	X.X	X.X	X.X
SEM		X	X	X	X.XX	X.XX	X.XX	X	X	X	X.XX	X.XX	X.XX
Minimum		X	X	X	X.XX	X.XX	X.XX	X	X	X	X.XX	X.XX	X.XX
Median		X	X	X	X.XXX	X.XXX	X.XXX	X	X	X	X.XXX	X.XXX	X.XXX
Maximum		X	X	X	X.XX	X.XX	X.XX	X	X	X	X.XX	X.XX	X.XX

Ratio = Treatment <Y>/Treatment <X>
Ratio = Treatment <Z>/Treatment <Y>

Notes for Generating the Actual Table:

Treatments for column headers:

- Treatment X: Suspension-Fasted
- Treatment Y: Tablet-Fasted
- Treatment Z: Tablet-Fed

Presentation of Data:

- AUC0-t, AUC0-96h, and Cmax will be presented in the same order, with same units, and same precision as in table shell <CPPar1>. Summary statistics for exposure based parameters will be to same precision as in table shell <CPPar1>.
- If AUC0-t equals AUC0-96h, then only AUC0-96h will be presented and a footnote (AUC0-t equals AUC0-96h.) will be added.

- n will be presented as an integer (with no decimal);
- All ratios will be presented to 2 decimals. Summary statistics for ratio will be presented to 2 decimal points for Mean, SD, SEM, and Median, Geom Mean; 1 decimal for CV%, Geom CV%.

```
Program:  /CAXXXXX/sas_prg/pksas/pk-ratio-tables.sas          DDMMMYYYY  HH:MM
Program:  /CAXXXXX/sas_prg/pksas/adam_ratio_pkparam.sas       DDMMMYYYY  HH:MM
```

Table CPStat1. Statistical Comparisons of Plasma CVN424 Pharmacokinetic Parameters: AUC0-t, AUC0-96h, and Cmax Table-Fasted Versus Suspension-Fasted (Pharmacokinetic Set)

		Treatment ------- Geometric LSMs -------				Geometric Mean	<90 or 95>%	<Intra or Inter>-subject
Parameter	(unit)	<X>	(n)	<Y>	(n)	Ratio	Confidence Intervals	CV%
Param1	(unit)	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX
Param2	(unit)	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX
Param3	(unit)	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX

Treatment <Y>: <Label for Second Treatment> (test)
Treatment <X>: <Label for First Treatment> (reference)
Parameters were ln-transformed prior to analysis.
Geometric least-squares means (LSMs) are calculated by exponentiating the LSMs from ANOVA.
Geometric Mean Ratio = 100*(test/reference)
Intra-subject CV% = 100 x (square root (exp[MSE]-1), where MSE = Residual variance from ANOVA.

Notes for Generating the Actual Table:

Treatments

- Suspension-Fasted
- Tablet-Fasted
- Tablet-Fed

Presentation of Data:

- Geometric LSMs be presented to same precision as Mean in the PK parameter table CPPar1,
- Geometric Mean Ratio, 90% CI and intra-subject CV% will be presented to 2 decimal places,

Programmers Note:

- PK Parameters are AUC0-t, AUC0-96h, and Cmax.
- If AUC0-t equals AUC0-96h, then only AUC0-96h will be presented and a footnote (AUC0-t equals AUC0-96h.) will be added.
- Comparison of interest for Table 14.2.1.8 is Tablet-Fasted versus Suspension-Fasted; for Table 14.2.1.9 is Tablet-Fed versus Suspension-Fasted, for Table 14.2.1.10 is Tablet-Fed versus Tablet-Fasted.

Program: /CAXXXXX/sas_prg/pksas/stats-tables-mixed.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_statsmixed.sas DDMMMYYYY HH:MM

Page X of X

Table CPStat2. Nonparametric Statistical Comparison of Plasma CVN424 Tmax and Tlag: Tablet-Fasted Versus Suspension-Fasted (Pharmacokinetic Set)

		Difference <X> - <Y>	
Parameter	Median	90% Confidence Interval	p-value
Tmax	X.XX	-X.XXXX - X.XXXX	X.XXXX
Tlag	X.XX	-X.XXXX - X.XXXX	X.XXXX

Treatment <X>: <Label for First Treatment>
Treatment <Y>: <Label for Second Treatment>

Notes for Generating the Actual Table:

Presentation of Data:

- The 90% confidence interval is constructed using Wilcoxon Singed rank test.
- Median difference will be presented to 2 decimals or 3 significant figures
- 90% CI will be presented to 4 decimals
- p-value will be presented to 4 decimals

Programmers Note:

- For Table 14.2.1.11, Tablet-Fasted is the test, Suspension-Fasted is reference. For Table 14.2.1.12, Tablet-Fed is the test, Suspension-Fasted is reference. For Table 14.2.1.13, Tablet-Fed is the test, Tablet-Fasted is reference.

Program: DM_PX:[HLXXXXX.PKSAS]XXXX.SAS DDMMMYYYY HH:MM

Table C(A)UPar3 Urinary Excretion of CVN424 Following Administration of 150 mg CVN424 Tablet-Fasted (Pharmacokinetic Set)

			Parameters							
			Predose		X – X Hours					
Subject Number	Treatment Sequence	Study Period	Conc (units)	Vol (units)	Conc (units)	Vol (units)	Aet1-t2 (units)	Ae (units)	fe (%)	CLR (units)
X	XXX	X	X.XX	X.XX	XX.XX	X.XX	X.XX	X.XX	X.XX	X.XX
X	XXX	X	X.XX	X.XX	XX.XX	X.XX	X.XX	X.XX	X.XX	X.XX
X	XXX	X	X.XX	X.XX	XX.XX	X.XX	X.XX	X.XX	X.XX	X.XX
n			X	X	X	X	X	X	X	X
Mean			X.XXX	X.XXX	XX.XXX	X.XXX	X.XXX	X.XXX	X.XXX	X.XXX
SD			X.XXXX	X.XXXX	XX.XXXX	X.XXXX	X.XXXX	X.XXXX	X.XXXX	X.XXXX
CV%			X.X	X.X	XX.X	X.X	X.X	X.X	X.X	X.X
SEM			X.XXXX	X.XXXX	XX.XXXX	X.XXXX	X.XXXX	X.XXXX	X.XXXX	X.XXXX
Minimum			X.XX	X.XX	XX.XX	X.XX	X.XX	X.XX	X.XX	X.XX
Median			X.XXX	X.XXX	XX.XXX	X.XXX	X.XXX	X.XXX	X.XXX	X.XXX
Maximum			X.XX	X.XX	XX.XX	X.XX	X.XX	X.XX	X.XX	X.XX
Geom Mean			X.XXX	X.XXX	XX.XXX	X.XXX	X.XXX	X.XXX	X.XXX	X.XXX
Geom CV%			X.X	X.X	XX.X	X.X	X.X	X.X	X.X	X.X

. = Value missing or not reportable.

Notes for Generating the Actual Table:

Presentation of Data:

- Concentrations and amounts will be presented to same precision as the bio concentration data. Volume will be presented to same precision as on the CRF. Note: If the amount of urine excreted was captured in the CRF as urine weight (g), it will be converted to volume (mL) using the assumed density of 1.00 g/mL.
- Fe will be presented to 2 decimal places. CLR and all other parameters will be presented to 3 significant figures.
- Summary statistics presentation: n = integer; Mean and Geom Mean +1; SD and SEM +2, Min/Max/Median +0, CV% and Geom CV% to 1 decimal.

Programmers Note:

- PK Parameters are: Ae0-12, Ae12-24, Ae24-48, and Ae48-96, Ae, fe, CLR
- Overall parameters are to be presented at the end of all the collection intervals, Ae, fe, CLR.

Program: DM_PX:[HLXXXXX.PKSAS]URINE-CONC-TABLES.SAS DDMMMYYYY HH:MM

Table CAES Treatment-Emergent Adverse Event Frequency by Treatment –
Number of Participants Reporting the Event (% of Participants Dosed) (Safety Set)

	Treatment			
Adverse Event	A (N = X)	B (N = X)	C (N = X)	Overall (N = X)
Number of Participants With TEAEs	X (X%)	X (XX%)	X (XX%)	X (XX%)
Number of Participants Without TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Eye disorders	X (X%)	X (X%)	X (X%)	<similar to
Vision blurred	X (X%)	X (X%)	X (X%)	previous columns>
Gastrointestinal disorders	X (X%)	X (X%)	X (X%)	
Dyspepsia	X (X%)	X (X%)	X (X%)	
Nausea	X (X%)	X (X%)	X (X%)	
Musculoskeletal and connective tissue disorders	X (X%)	X (X%)	X (X%)	
Back pain	X (X%)	X (X%)	X (X%)	
Muscle cramps	X (X%)	X (X%)	X (X%)	
Musculoskeletal pain	X (X%)	X (X%)	X (X%)	
Nervous system disorders	X (X%)	X (X%)	X (X%)	
Headache	X (X%)	X (X%)	X (X%)	

Treatment A: < >
Treatment B: < >
Treatment C: < >
Although a participant may have had 2 or more adverse events, the participant is counted only once within a category. The same participant may appear in different categories.
Adverse events are classified according to MedDRA Version 25.1.
TEAEs = Treatment-emergent adverse event

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CAEF Treatment-Emergent Adverse Event Frequency by Treatment –
Number of Adverse Events (% of Total Adverse Events) (Safety Set)

	Treatment			
Adverse Event	A	B	C	Overall
Number of TEAEs	X	X	X	X
Eye disorders	X (X%)	X (X%)	X (X%)	<similar to
Vision blurred	X (X%)	X (X%)	X (X%)	previous
Gastrointestinal disorders	X (X%)	X (X%)	X (X%)	column>
Dyspepsia	X (X%)	X (X%)	X (X%)	
Nausea	X (X%)	X (X%)	X (X%)	
Musculoskeletal and connective tissue disorders	X (X%)	X (X%)	X (X%)	
Back pain	X (X%)	X (X%)	X (X%)	
Muscle cramps	X (X%)	X (X%)	X (X%)	
Musculoskeletal pain	X (X%)	X (X%)	X (X%)	
Nervous system disorders	X (X%)	X (X%)	X (X%)	
Headache	X (X%)	X (X%)	X (X%)	

Treatment A: < >
Treatment B: < >
Treatment C: < >
Adverse events are classified according to MedDRA Version 25.1.
TEAEs = Treatment-emergent adverse events

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CAESR Treatment-Emergent Adverse Event Frequency by Treatment, Severity, and Relationship to Study Product - Number of Adverse Events (Safety Set)

Adverse Event	Treatment	Number of Participants With TEAEs	Number of TEAEs	Severity			Relationship to Study Product	
				Mild	Moderate	Severe	Related	Unrelated
Abdominal pain	A	X	X	X	X	X	X	X
Constipation	C	X	X	X	X	X	X	X
Dry throat	B	X	X	X	X	X	X	X
Dysmenorrhoea	C	X	X	X	X	X	X	X
Dyspepsia	B	X	X	X	X	X	X	X
Headache	A	X	X	X	X	X	X	X
	C	X	X	X	X	X	X	X
Myalgia	A	X	X	X	X	X	X	X
Nasal congestion	B	X	X	X	X	X	X	X
Skin laceration	B	X	X	X	X	X	X	X
	A	X	X	X	X	X	X	X
	B	X	X	X	X	X	X	X
	C	X	X	X	X	X	X	X
	Overall	X	X	X	X	X	X	X

Treatment A: < >
Treatment B: < >
Treatment C: < >
Adverse events are classified according to MedDRA Version 25.1.
TEAEs = Treatment-emergent adverse events

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table 14.3.2.1 Serious Adverse Events (Safety Set)

Will match format of Appendix 16.2.7

Or contain statement as follows:

"There were no events that met this criteria."

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CLBO Out-of-Range Values and Recheck Results - <Clinical Laboratory Panel> (Safety Set)

Participant Number	Age/ Sex	Study Period	Treatment	Day	Hour	Date	Time	Parameter1 <Range> (Unit)	Parameter2 <Range> (Unit)	Parameter3 <Range> (Unit)	Parameter4 <Range> (Unit)
X	XX/X	Screen				DDMMMYYYY	HH:MM:SS	XX H		XX L	XX H
		1	X	-X	-X.XX	DDMMMYYYY	HH:MM:SS	XX L	XX L		XX L

Programmer Note: Replace Parameter1, 2 etc. with actual lab tests in the study. Sort unscheduled assessment and early termination chronologically with other scheduled assessments and rechecks. Recheck should be sorted with the scheduled time point the recheck is for. Unscheduled and Early Termination records should only be included if they are out of range or recheck results.

Treatment A: < >
Treatment B: < >
Treatment C: < >
F = Female; M = Male
H = Above reference range; L = Below reference range

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CLBD Clinical Laboratory Summary and Change From Baseline – <Clinical Laboratory Panel> (Safety Set)

				Treatment			
Laboratory Test (units)	Reference Range	Time Point	Statistic	A (N = X)	B (N = X)	C (N = X)	Overall
Testname (unit)	< - >#	Baseline	n	X	X	X	
			Mean	X.X*	X.X	X.X	
			SD	X.XX	X.XX	X.XX	
			Minimum	XX	XX	XX	
			Median	X.X	X.X	X.X	
			Maximum	XX	XX	XX	
		Day 2	n	X	X	X	X
			Mean	X.X	X.X^	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX
		Change Day 2	<same as above>				

Programmer Note: Treatment means at specific time points will be flagged (with a *) if they are above or below the reference range. This only applies to the clinical laboratory treatment results (i.e., not the change from baseline or any other endpoints). Time Point column will match those found in Section 7 of the SAP.

Treatment A: < >
Treatment B: < >
Treatment C: < >
Baseline is the last measurement collected prior to dose for the respective treatment. Overall will use treatment specific change from baselines.
= Lowest of the lower ranges and highest of the higher ranges are used. Refer to Appendix 16.1.10.1 for the breakdown.
* = Above reference range; ^ = Below reference range

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CLBS Clinical Laboratory Shift From Baseline - Serum Chemistry (Safety Set)

			Baseline L			Baseline N			Baseline H		
			Postdose			Postdose			Postdose		
Laboratory Test (units)	Treatment	Time Point	L	N	H	L	N	H	L	N	H
Testname (unit)	A	Day 2	X	XX	X	X	XX	X	X	XX	X
		Day 3	X	XX	X	X	XX	X	X	XX	X
		Day 5	X	XX	X	X	XX	X	X	XX	X
	B	Day 2	X	XX	X	X	XX	X	X	XX	X
		Day 3	X	XX	X	X	XX	X	X	XX	X
		Day 5	X	XX	X	X	XX	X	X	XX	X
	<Same for Treatment C>										

Programmer Note: Time Point column will match those found in Section 7 of the SAP. For urinalysis, the following footnote is used since the categories of N and O will be used instead of L, N, H:
N = Within reference range; O = Outside reference range

Treatment A: < >
Treatment B: < >
Treatment C: < >
Baseline is the last measurement collected prior to dose for the respective treatment.
N = Within reference range; L = Below reference range; H = Above reference range

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CVS Vital Sign Summary and Change From Baseline (Safety Set)

				Treatment			
				A	B	C	Overall
Vital Sign (units)	Time Point		Statistic	(N = X)	(N = X)	(N = X)	(N = X)
Testname (unit)	Baseline		n	X	X	X	
			Mean	X.X	X.X	X.X	
			SD	X.XX	X.XX	X.XX	
			Minimum	XX	XX	XX	
			Median	X.X	X.X	X.X	
			Maximum	XX	XX	XX	
	Hour 1.5	Absolute	n	X	X	X	X
			Mean	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX
		Change	n	X	X	X	X
			Mean	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX

Programmer Note: Time Point column will match those found in Section 7 of the SAP. Please note that all timepoints will follow in a similar manner. Parameters will be in this order: Diastolic Supine, Diastolic Standing, Orthostatic (Diastolic), Systolic Supine, Systolic Standing, Orthostatic (Systolic), Heart Rate Supine, Heart Rate Standing, Orthostatic (Heart Rate), Respiration, Temperature.

Treatment A: < >
Treatment B: < >
Treatment C: < >
Baseline is the last measurement collected prior to dose for the respective treatment. The average is used for supine values when triplicates are recorded. Orthostatic change = Standing – Supine (averages, when applicable)

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CEG 12-Lead Electrocardiogram Summary and Change From Baseline (Safety Set)

			Treatment			
			A	B	C	
Measurement (units)	Time Point	Statistic	(N = X)	(N = X)	(N = X)	Overall
Testname (unit)	Baseline	n	X	X	X	
		Mean	X.X*	X.X	X.X	
		SD	X.XX	X.XX	X.XX	
		Minimum	XX	XX	XX	
		Median	X.X	X.X	X.X	
		Maximum	XX	XX	XX	
	Hour 3	n	X	X	X	X
		Mean	X.X	X.X^	X.X	X.X
		SD	X.XX	X.XX	X.XX	X.XX
		Minimum	XX	XX	XX	XX
		Median	X.X	X.X	X.X	X.X
		Maximum	XX	XX	XX	XX
	Change Hour 3	<same as above>				

Treatment A: < >
Treatment B: < >
Treatment C: < >
Baseline is the average of the triplicate collected prior to dose for the respective treatment. Overall will use treatment specific change from baselines.
Summaries are based on the average of the triplicates.

Programmer Note: Time Point column will match those found in Section 7 of the SAP.

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CEGC 12-Lead Electrocardiogram – Categorical Summary (Safety Set)

			Treatment			
	Timepoint	Result	A (N = X)	B (N = X)	C (N = X)	Overall (N = X)
	Baseline	Abnormal, CS	X (X%)	X (X%)	X (X%)	X (X%)
		Abnormal, NCS	<Same as previous row>			
		Within Normal Limits				
	Hour 3	<same as above>				

Treatment A: < >
Treatment B: < >
Treatment C: < >
Result is the worst of the triplicates.

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

11. LISTING SHELLS

The following listing shells provide a framework for the display of data from this study. The shells may change due to unforeseen circumstances. These shells may not be reflective of every aspect of this study, but are intended to show the general layout of the listings that will be presented and included in the final report. Listings will generated from data created in accordance with SDTM Model 1.4 with Implementation Guide 3.2 or CDASH data structure. All listings will be presented in Courier New size font 9. Time point information (period, day, hour) will match that found in the CRF.

While not noted on the shells, source footnotes will be included to reference the data domains support the SAS output.

Appendix 16.1.10.1 Clinical Laboratory Reference Ranges

Laboratory Group	Test Name	Sex	Age Category	Reference Range	Unit
Serum Chemistry	Testname1	MALE		XX - XXX	mEq/L
	Testname2	MALE	0-25	XX - XXX	U/L
			26-99	XX - XXX	U/L
<similar for all other tests, note that age will only be presented when different reference range exists>					
Hematology	<similar to serum chemistry>				
Urinalysis	Testname	MALE		NEGATIVE	
Urine Drug Screening	Amphetamines	MALE		NOT DETECTED	

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendices 16.2.1.1 and 16.2.1.2 will be in the following format:

Page 1 of X

Appendix 16.2.1.1 Participant Disposition (Safety Set)

Participant Number	Randomized/ Actual Treatment Sequence	End of Treatment: Did Subject Prematurely Discontinue?	End of Treatment: Treatment Discontinuation Date	End of Treatment: Primary Treatment Discontinuation Reason	End of Treatment: Specify	End of Study: Did Subject Complete the Study?	End of Study: Date of Completion/ Discontinuation	End of Study: Primary Study Discontinuation Contact	End of Study: Specify
1	ABC/ABC	No				Yes	DDMMMYYYY		
2	XXX/XXX	No				No	DDMMMYYYY	Personal Reason	XXXXXXX
3	XXX/X	Yes	DDMMMYYYY	Adverse Event	XXXXXXXXXXX	No	DDMMMYYYY	Other	XXXXXX

Treatment A: a single oral dose of 150 mg CVN424 suspension under fasted condition
Treatment B: a single oral dose of 150 mg CVN424 tablet under fasted condition
Treatment C: a single oral dose of 150 mg CVN424 tablet under fed condition

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendices 16.2.4.1 and 16.2.4.2 will be in the following format:

Page 1 of 1

Appendix 16.2.4.1 Demographics (Safety Set)

Participant Number	Year Of Birth	Age (yr)	Sex	Race	Ethnicity	Height (cm)	Weight (kg)	Body Mass Index (kg/m²)	Informed Consent Date
1	YYYY	47	Male	< >	Not Hispanic or Latino	XXX	XX.X	XX.XX	DDMMMYYYY
2	<similar to above.								

Age is approximated as year of informed consent – year of birth. There will be a subtraction of 1 if the difference in years is 1 more than the age specified in the inclusion criteria.

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Programmer Note: Height, weight, and BMI will not be included in 16.2.4.2.

Appendices 16.2.4.3 and 16.2.4.4 will be in the following format:

Appendix 16.2.4.3 Physical Examination (I of II) (Safety Set)

Participant Number	Study Period	Treatment	Day	Hour	Date	Type	Was Physical Exam Performed?	System1	System2	System3	System4	System5	System6
X	Screen				DDMMMYYYY	Full	Yes	NORMAL	NORMAL	NORMAL	NORMAL	NORMAL	NORMAL
	X	A	X	XX.XX	DDMMMYYYY	Symptom	Yes	CHANGED*	UNCHANGED	UNCHANGED	UNCHANGED	UNCHANGED	NORMAL

Treatment A: < >
Treatment B: < >
Treatment C: < >
* See Appendix 16.2.4.5 Physical Examination Description
HEENT = Head, Eyes, Ears, Nose, Throat

Program: /CAXXXX/sas_prg/stsas/programname2022Q1.sas DDMMMYYYY HH:MM

Appendix 16.2.4.5 Physical Examination Descriptions (Safety Set)

Participant Number	Study Period	Treatment	Day	Hour	Date	System	Result	Comment
X	1	A	X	XX.XX	DDMMMYYYY	Skin	ABNORMAL	RIGHT CHEST SCAR-NCS

HEENT = Head, eyes, ears, nose, throat

Program: /CAXXXX/sas_prg/stsas/programname2022Q1.sas DDMMMYYYY HH:MM

Appendix 16.2.4.6 Medical History (Safety Set)

Participant Number	Any History?	Condition or Event	Date		
			Start	End	Ongoing?
1	No				
2	Yes	< >	YYYY		YES
			<note date can be YYYY, MONYYYY, or DDMONYYYY based on individual subject data>		

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.4.7 Substance Use (Safety Set)

Participant Number	Substance	Description of Use	Start Date	End Date
1	Tobacco Use	0-4 CIGARETTES WEEK	DDMONYYYY	DDMONYYYY
		NON-SMOKER	DDMONYYYY	
2	Tobacco Use	NON-SMOKER	DDMONYYYY	

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendices 16.2.5.1 and 16.2.5.2 will be in the following format:

Page 1 of 1

Appendix 16.2.5.1 Subject Eligibility (Safety Set)

Participant Number	Study Period	Did subject meet all eligibility criteria?	Criterion Not Met	Specify
1	Screen	YES		
2	Screen	NO	Exclusion 5	<specify and criterion not met will only be presented if populated>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.5.3 Test Compound Description

CRF Treatment Description	Form	Route
< >	SOLUTION	ORAL

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.5.4 Test Compound Administration Times (Safety Set)

Participant Number	Study Period	Treatment	Day	Hour	Dose Date	Dose Time	Compound	Planned Dosage	Comments
1	1	A	1	0.00	DDMONYYYY	HH:MM:SS	< >	500 NCI	<This column prints only if data is

Treatment A: < >
Treatment B: < >
Treatment C: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.5.5 Meal Times (Safety Set)

Participant Number	Study Period	Treatment	Day	Hour	Interval	Event	Start Date	Start Time	Stop Date	Stop Time	Comment
1	1	C	-1	-15.0	-0.5 to -0.33	DINNER	DDMONYYYY	HH:MM:SS	DDMONYYYY	HH:MM:SS	
				-11.0		SNACK	DDMONYYYY	HH:MM:SS	DDMONYYYY	HH:MM:SS	
			1	4.1		LUNCH	DDMONYYYY	HH:MM:SS	DDMONYYYY	HH:MM:SS	

Treatment C: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.5.6 Prior and Concomitant Medications (Safety Set)

Participant Number	Treatment	Prior?	Medication (WHO DD)	Dosage	Route	Start Date	Start Time	End Date	End Time	Frequency	Indication	Ongoing?
1			None									
2			None									
3		Yes	CETIRIZINE (CETIRIZINE)	X MG	BY MOUTH	DDMONYYYY		DDMONYYYY	HH:MM	XXXXXXX	XXXXXXX	NO
	B	No	PARACETAMOL (PARACETAMOL)	X MG	XXXXXXXXX	DDMONYYYY	HH:MM	XXXXXXXXX	HH:MM	XXXXXXXX	XXXXXXXX	XX

Treatment A: < >
Treatment B: < >
Treatment C: < >
Concomitant medications are coded with WHO Drug Dictionary Version 01-Sep-2022 b3.
WHO DD = World Health Organization Drug Dictionary
Prior is defined as a medication administered prior to the first study drug administration.

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.5.7 Pharmacokinetic Blood Draw Times and Concentration Data (Safety Set)

Study Sequence	Subject Number	Study Period	Treatment	CRF Day	CRF Hour	Blood Draw Date	Blood Draw Time	Elapsed Time From Last Dose (Hour)	<Analyte 1> Concentration (units)	Comments
1	1	1	A	1	-0.05	DDMONYYYY	HH:MM:SS	0.0	X.XX	
					0.50	DDMONYYYY	HH:MM:SS	0.565	X.XX	
					1.00	DDMONYYYY	HH:MM:SS	1.090	X.XX	Late Draw
			< >							
<similar for all other time points and subjects>										

Treatment A: < >
Treatment B: < >
Treatment C: < >

Program: /CAXXXXX/sas_prg/pksas/standardlis/pk_bld.sas DDMMMYYYY HH:MM
Programmer Notes:

- Population: Safety set will be used in this listing.
- If SS are not present in Time in the EDC/offsite studies, then Time may be presented as HH:MM.

Appendix 16.2.5.8 Pharmacokinetic Urine Collection (Safety Set)

Study Sequence	Subject Number	Study Period	Treatment	CRF Collection		Urine Collection						
				End Day	Interval	Start Date	Start Time	Stop Date	Stop Time	Analyte> Concentration (units)	Urine Weight (g)	Comments
1	1	1	B	1	-1.50	DDMONYYYY	HH:MM:SS	DDMONYYYY	HH:MM:SS	XXXX	X.XX	No void
					0.00 - 4.00	DDMONYYYY	HH:MM:SS	DDMONYYYY	HH:MM:SS	XXXX	X.XX	Unknown amount of urine spilled
			<>									
				4	48.00 - 96.00	<similar to above for all time points and subjects>						

Treatment B: < >

Program: /CAXXXXX/sas_prg/pksas/standardlis/pk_urn.sas DDMMMYYYY HH:MM

Programmer Notes:

- Population: Safety set will be used in this listing.
- If SS are not present, then Time may be presented as HH:MM.

Table CPKel1 Intervals (Hours) Used for Determination of Plasma CVN424 Kel Values (Pharmacokinetic Set)

Subject Number	Treatment Sequence	Treatment <X> Interval	Treatment <X> R2	Treatment <X> n	Treatment <Y> Interval	Treatment <Y> R2	Treatment <Y> n
X	XX	XX.X - XX.X	X.XXX	X	XX.X - XX.X	X.XXX	X
X	XX	XX.X - XX.X	X.XXX	X	XX.X - XX.X	X.XXX	X
X	XX	XX.X - XX.X	X.XXX	X	XX.X - XX.X	X.XXX	X
X	XX	XX.X - XX.X	X.XXX	X	XX.X - XX.X	X.XXX	X
X	XX	XX.X - XX.X	X.XXX	X	XX.X - XX.X	X.XXX	X
X	XX	XX.X - XX.X	X.XXX	X	XX.X - XX.X	X.XXX	X

R2 = Coefficient of determination
n = Number of points used in Kel calculation
. = Kel value not reportable.

Notes for Generating the Actual Table:

Treatmen columns: Suspension-Fasted, Tablet-Fasted, Tablet-Fed

Presentation of Data:

- Interval start and stop times will be presented to 1 decimal or 3 sig figures min;
- R2 will be presented to 3 decimals;
- n will be presented as an integer (with no decimal)

Programmer note:
Use long treatment descriptions for footers

Program: /CAXXXXX/sas_prg/pksas/adam_kel.sas DDMMMYYYY HH:MM

Appendix 16.2.7.3 will resemble Appendix 16.2.7.1

Appendix 16.2.7.1 Adverse Events (Safety Set)

Participant Number	Age/ Sex	Treatment	TE?	System Organ Class/ Preferred Term (Verbatim)	Time From Last Dose (DD:HH:MM)	Date:Time Start/ End Duration (DD:HH:MM)	Serious/ Outcome	Severity/ Frequency	Study Product Relationship/ Action	Related Study Procedure
1	30/F			None						
2	24/M			None						
3	52/M	A	Yes	XXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX (XXXXXXXXXXX)	XX:XX:XX	DDMONYYYY:HH:MM/ DDMONYYYY:HH:MM 00:23:15	No/ Recovered/ Resolved	Moderate/ Intermittent	Related/ Drug Withdrawn	XXXXX
		B	Yes	<similar to above>						

Programmer Note: AEs should be presented start date/time order for each subject.

Treatment A: < >
Treatment B: < >
Treatment C: < .
Adverse events are classified according to MedDRA Version 25.1.
TE = Abbreviation for treatment-emergent
F = Female; M = Male

Programmer note: Treatment and TE columns will not be included in 16.2.7.3

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.7.4 will resemble Appendix 16.2.7.2

Appendix 16.2.7.2 Details for Serious Adverse Events (Safety Set)

Participant Number	Age/ Sex	Treat-ment	TE?	System Organ Class/ Preferred Term (Verbatim)	Date:Time Start/ End Duration (DD:HH:MM)	Serious Event?	Congenital Anomaly/ Birth Defect?	Persistent or Significant Disability or Incapacity?	Hospital-ization?	Life-Threat?	Important Medical Event?	Death?
3	52/M	A	Yes	XXXXXXXXXXX/ XXXXXXXXXXXXXXXXX (XXXXXXXXXXX)	DDMONYYYY:HH:MM/ DDMONYYYY:HH:MM 00:23:15	Yes	No	No	Yes	No	Yes: < >	No

Programmer Note: If Serious = Yes then present AEs in this listing otherwise please do not include this listing.

Treatment A: < >
Treatment B: < >
Treatment C: < >
Adverse events are classified according to MedDRA Version 25.1.
TE = Abbreviation for treatment-emergent
F = Female; M = Male

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendices 16.2.8.2 – 16.2.8.6 will resemble 16.2.8.1.

Appendix 16.2.8.1 Clinical Laboratory Report - Serum Chemistry (Safety Set)

Participant Number	Age/ Sex	Study Period	Treat-ment	Day	Hour	Date	Time	Chloride M: 97-105 (mEq/L)	Potassium M: 3.7-5.2 (mEq/L)	Phosphorus M: 2.4-4.4 (mg/dL)	Sodium M: 135-143 (mEq/L)
1	XX/M	Screen				DDMONYYYY	HH:MM:SS	XXX	X.X	X.X	XXX H
		1	A	1	-17.00	DDMONYYYY	HH:MM:SS	XXX H	X.X	X.X	XXX H
		Recheck				DDMONYYYY	HH:MM:SS	XXX	X.X	X.X	XXX

<similar to above for all subjects/time points>

Treatment A: < >
Treatment B: < >
Treatment C: < >
F = Female; M = Male
H = Above reference range

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.8.7 Vital Signs (Safety Set)

Participant Number	Age/ Sex	Study Period	Treatment	Day	Hour	Date	Time	Blood Pressure (mmHg) Position	Blood Pressure (mmHg) Sys/Dia	Pulse (bpm)	Respiration (brpm)	Temperature (°C)	Weight (kg)
1	30/F	Screen				DDMONYYYY	HH:MM:SS						XX.X
								XXXX	XXX/ XX	XX	XX	XX.X	
							R HH:MM:SS	XXXX	XXX/ XX				
							R HH:MM:SS	XXXX	XXX/ XX				
		1	A	-1	-0.83	DDMONYYYY	HH:MM:SS	XXXX	XXX/ XX				
								AVG SUP	XXX/ XX				
								STD3	XXX/ XX				

Treatment A: < >
Treatment B: < >
Treatment C: < >
F = Female; M = Male
SUP1 = 1-minute supine; SUP3 = 3-minute supine; STD3 = 3-minute standing; R = Recheck value; brpm = breaths/min

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.8.8 Orthostatic Vital Signs (Safety Set)

Subject Number	Age/ Sex	Study Period	Treatment	Day	Hour	Blood Pressure (mmHg) Systolic	Blood Pressure (mmHg) Diastolic	Heart Rate (bpm)
1	30/F	1	A		Baseline	XX	-XX	XX
				1	2.00	XX	XX	XX
				<similar to above>				

Treatment A: < >
Treatment B: < >
Treatment C: < >
This listing only presents orthostatic changes used during analysis.
F = Female; M = Male
Baseline is the last measurement collected prior to dose for the respective treatment.
Orthostatic Change = standing – supine, average as applicable

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.8.9 12-Lead Electrocardiogram (Safety Set)

Participant Number	Age/ Sex	Study Period	Treatment	Day	Hour	Date	Time	Result	Heart Rate (bpm)	RR (msec)	PR (msec)	QRS (msec)	QT (msec)	QTcB (msec)	QTcF (msec)	Specify/Comments
1	30/F	Screen				DDMONYYYY	X:XX:XX	WNL	XX	XXX	XX	XX	XXX	XXX	XXX	XXXXXXXXX
1			A	-1	X.XX	DDMONYYYY	XX:XX:XX	ANCS	XX	XXX	XX	XX	XXX	XXX @	410	
				8	X.XX	DDMONYYYY	XX:XX:XX	< >	XX	XXX	XX	XX	XXX	XXX	441 @	XXXXXXXXXXX
				8	X.XX R	DDMONYYYY	XX:XX:XX	< >	XX	XXX	XX	XX	XXX	XXX	451 @	

Treatment A: < >
Treatment B: < >
Treatment C: < >
F = Female; M = Male
R = Recheck value; WNL = Within normal limits; ANCS = Abnormal, not clinically significant
# = QTc value greater than 450 msec
QTcF = QT corrected for heart rate using Fridericia's correction, QTcB = QT corrected for heart rate using Bazett’s correction.

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.8.10 12-Lead Electrocardiogram – Average of Triplicates (Safety Set)

Subject Number	Age/ Sex	Study Period	Treatment	Day	Hour	Heart Rate (bpm)	RR (msec)	PR (msec)	QRS (msec)	QT (msec)	QTcB (msec)	QTcF (msec)	Result
1	30/F	1	A		Baseline	XX.X	XX.X	XX.X	XX.X	XX.X	XXX.X	410.2	WNL
				8	X.XX	XX.X	XX.X	XX.X	XX.X	XX.X	XXX.X	451.4 #@	ANCS

Programmer Note: Averaged triplicate values will be displayed to the nearest tenth.

Treatment A: < >
Treatment B: < >
Treatment C: < >
This listing only presents average triplicate 12-lead electrocardiogram results used during analysis which includes the worst of the categorical results (WNL = within normal limits, ANCS = Abnormal Not Clinically Significant, ACS = Abnormal Clinically Significant).
Baseline is the last measurement collected prior to dose for the respective treatment.
F = Female; M = Male
QTcF = QT corrected for heart rate using Fridericia's correction, QTcB = QT corrected for heart rate using Bazett’s correction.
# = QTc value greater than 450 msec; @ = QTc change from baseline greater than 30 msec

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendices 16.2.8.11 and 16.2.8.13 will be in the following format:

```
                                                                                                          Page 1 of X
                      Appendix 16.2.8.11 Columbia-Suicide Severity Rating Scale (C-SSRS) Questions - Baseline/Screening

 Question
 Number       Question
---------------------------------------------------------------------------------------------------------------------------
   1.0        XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
   1.1        XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX





Program:  /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas  DDMONYYYY   HH:MM
```

Appendices 16.2.8.12 and 16.2.8.14 will be in the following format:

Page 1 of X

Appendix 16.2.8.12 Columbia-Suicide Severity Rating Scale (C-SSRS) Responses - Baseline/Screening (Safety Set)

Participant Number	Study Period	Treatment	Day	Hour	Date	Question Number	Result
1	Screen				DDMMMYYYY	1.0	YES/NO
						1.1	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Programmer Note: Please don't include Treatment, Day, and Hour columns in Appendix 16.2.8.12 (should be included in Appendix 16.2.8.14).

Treatment A: < >
Treatment B: < >
Treatment C: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

16.1.9.2 Statistical Outputs

Treatment A: A single oral dose of 150 mg CVN424 suspension under fasted condition
Treatment B: A single oral dose of 150 mg CVN424 tablet under fasted condition
Treatment C: A single oral dose of 150 mg CVN424 tablet under fed condition
APERIOD: Study period; TRTSEQP: Planned treatment sequence
AIC: Akaike Information Criterion; BIC: Bayesian Information Criterion; AICC: Corrected Akaike Information Criterion
Program: /CA38736/sas_prg/pksas/adam_statsmixed.sas 08MAR2023 19:49

Treatment A: A single oral dose of 150 mg CVN424 suspension under fasted condition
Treatment B: A single oral dose of 150 mg CVN424 tablet under fasted condition
Treatment C: A single oral dose of 150 mg CVN424 tablet under fed condition
APERIOD: Study period; TRTSEQP: Planned treatment sequence
AIC: Akaike Information Criterion; BIC: Bayesian Information Criterion; AICC: Corrected Akaike Information Criterion
Program: /CA38736/sas_prg/pksas/adam_statsmixed.sas 08MAR2023 19:49

Treatment A: A single oral dose of 150 mg CVN424 suspension under fasted condition
Treatment B: A single oral dose of 150 mg CVN424 tablet under fasted condition
Treatment C: A single oral dose of 150 mg CVN424 tablet under fed condition
APERIOD: Study period; TRTSEQP: Planned treatment sequence
AIC: Akaike Information Criterion; BIC: Bayesian Information Criterion; AICC: Corrected Akaike Information Criterion
Program: /CA38736/sas_prg/pksas/adam_statsmixed.sas 08MAR2023 19:49

Treatment A: A single oral dose of 150 mg CVN424 suspension under fasted condition
Treatment B: A single oral dose of 150 mg CVN424 tablet under fasted condition
Treatment C: A single oral dose of 150 mg CVN424 tablet under fed condition
APERIOD: Study period; TRTSEQP: Planned treatment sequence
AIC: Akaike Information Criterion; BIC: Bayesian Information Criterion; AICC: Corrected Akaike Information Criterion
Program: /CA38736/sas_prg/pksas/adam_statsmixed.sas 08MAR2023 19:49

Treatment A: A single oral dose of 150 mg CVN424 suspension under fasted condition
Treatment B: A single oral dose of 150 mg CVN424 tablet under fasted condition
Treatment C: A single oral dose of 150 mg CVN424 tablet under fed condition
APERIOD: Study period; TRTSEQP: Planned treatment sequence
AIC: Akaike Information Criterion; BIC: Bayesian Information Criterion; AICC: Corrected Akaike Information Criterion
Program: /CA38736/sas_prg/pksas/adam_statsmixed.sas 08MAR2023 19:49

Treatment A: A single oral dose of 150 mg CVN424 suspension under fasted condition
Treatment B: A single oral dose of 150 mg CVN424 tablet under fasted condition
Treatment C: A single oral dose of 150 mg CVN424 tablet under fed condition
APERIOD: Study period; TRTSEQP: Planned treatment sequence
AIC: Akaike Information Criterion; BIC: Bayesian Information Criterion; AICC: Corrected Akaike Information Criterion
Program: /CA38736/sas_prg/pksas/adam_statsmixed.sas 08MAR2023 19:49

Treatment A: A single oral dose of 150 mg CVN424 suspension under fasted condition
Treatment B: A single oral dose of 150 mg CVN424 tablet under fasted condition
Treatment C: A single oral dose of 150 mg CVN424 tablet under fed condition
APERIOD: Study period; TRTSEQP: Planned treatment sequence
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Treatment A: A single oral dose of 150 mg CVN424 suspension under fasted condition
Treatment B: A single oral dose of 150 mg CVN424 tablet under fasted condition
Treatment C: A single oral dose of 150 mg CVN424 tablet under fed condition
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Treatment A: A single oral dose of 150 mg CVN424 suspension under fasted condition
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Program: /CA38736/sas_prg/pksas/adam_statsmixed.sas 08MAR2023 19:49

Treatment A: A single oral dose of 150 mg CVN424 suspension under fasted condition
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Program: /CA38736/sas_prg/pksas/adam_statsmixed.sas 08MAR2023 19:49

Treatment A: A single oral dose of 150 mg CVN424 suspension under fasted condition
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Program: /CA38736/sas_prg/pksas/adam_statsmixed.sas 08MAR2023 19:49

Treatment A: A single oral dose of 150 mg CVN424 suspension under fasted condition
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Program: /CA38736/sas_prg/pksas/adam_statsmixed.sas 08MAR2023 19:49

B = A single oral dose of 150 mg CVN424 tablet under fasted condition
A = A single oral dose of 150 mg CVN424 suspension under fasted condition
Program: /CA38736/sas_prg/pksas/adam_statsnonpar.sas 08MAR2023 19:49

B = A single oral dose of 150 mg CVN424 tablet under fasted condition
A = A single oral dose of 150 mg CVN424 suspension under fasted condition
Program: /CA38736/sas_prg/pksas/adam_statsnonpar.sas 08MAR2023 19:49

B = A single oral dose of 150 mg CVN424 tablet under fasted condition
A = A single oral dose of 150 mg CVN424 suspension under fasted condition
Program: /CA38736/sas_prg/pksas/adam_statsnonpar.sas 08MAR2023 19:49

B = A single oral dose of 150 mg CVN424 tablet under fasted condition
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Program: /CA38736/sas_prg/pksas/adam_statsnonpar.sas 08MAR2023 19:49

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Program: /CA38736/sas_prg/pksas/adam_statsnonpar.sas 08MAR2023 19:49

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Program: /CA38736/sas_prg/pksas/adam_statsnonpar.sas 08MAR2023 19:49

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Program: /CA38736/sas_prg/pksas/adam_statsnonpar.sas 08MAR2023 19:49

C = A single oral dose of 150 mg CVN424 tablet under fed condition
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Program: /CA38736/sas_prg/pksas/adam_statsnonpar.sas 08MAR2023 19:49

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Program: /CA38736/sas_prg/pksas/adam_statsnonpar.sas 08MAR2023 19:49

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Program: /CA38736/sas_prg/pksas/adam_statsnonpar.sas 08MAR2023 19:49

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Program: /CA38736/sas_prg/pksas/adam_statsnonpar.sas 08MAR2023 19:49

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Program: /CA38736/sas_prg/pksas/adam_statsnonpar.sas 08MAR2023 19:49

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Program: /CA38736/sas_prg/pksas/adam_statsnonpar.sas 08MAR2023 19:49

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