Table of Contents

STATISTICAL ANALYSIS PLAN

**A Phase 1, Drug-Drug Interaction Study
to Evaluate the Safety, Tolerability,
and the Induction potential of TBAJ-876 on CYP3A4 and P-glycoprotein
and the Inhibition potential of TBAJ-876 on P-glycoprotein
in Healthy Adult Subjects**

**Protocol No: TBAJ-876-CL002
TKL Study Number P1980322**

**TKL Research, Inc
One Promenade Blvd
Fair Lawn, NJ 07410**

14 December 2022

DocuSigned by:
Jerry Nedelman
Signer Name: Jerry Nedelman
Signing Reason: I have reviewed this document
Signing Time: 12/16/2022 | 8:01:56 AM PST
7839E5A76523498AB928E27ED5F738EA

Signature 12/16/2022 **Date**

**Jerry Nedelman
Senior Director, Pharmacometrics
TB Alliance**

DocuSigned by:
Michael Tuley
Signer Name: Michael Tuley
Signing Reason: I approve this document
Signing Time: 12/16/2022 | 8:01:37 AM PST
BE981D7A319443499E30D520D1EBB3FD

Signature 12/16/2022 **Date**

**Michael Tuley, PhD
Vice President, Data Sciences and Quality Assurance
TKL Research, Inc.**

Table of Contents

List of Abbreviations and Definitions of Terms

Abbreviation	Definition
ADaM	Analysis Data Model
AE	Adverse Event
ANOVA	Analysis of variance
AUC	Area under the curve
CI	Confidence interval
CRF	Case Report Form
DMP	Data Management Plan
ECG	Electrocardiogram
ET	Early termination
GMR	Ratio of geometric means
ODS	Output Delivery System
PK	Pharmacokinetics
PT	Preferred Term
RTF	Rich-Text Format
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SDTM	Study Data Tabulation Model
SOC	System Organ Class
SOP	Standard Operating Procedure
TEAE	Treatment-emergent adverse event

1. INTRODUCTION

This Statistical Analysis Plan (SAP) is based on the study protocol dated 20 May 2022. This document specifies, in advance of data collection, a comprehensive description of the analysis methods planned to achieve the study objectives specified in the study protocol. Two sequential study phases are planned, with the performance of the second phase conditional on the outcome of the first. The present document will show the planned data presentations, summaries, and analyses for the initial phase of the study. A similar document will be prepared separately in the event that the study enters its second phase.

2. STUDY OBJECTIVES

The primary objective of the study is to evaluate the induction potential of TBAJ-876 on CYP3A4 and P-glycoprotein and the inhibition potential of TBAJ-876 on P-glycoprotein in healthy adult subjects.

The secondary objective of the study is to evaluate the effects of multiple-dose administrations of TBAJ-876 on the safety and tolerability of midazolam and digoxin. An extension of the study is planned conditionally on the outcomes of the initial phase, the objective of which will be to evaluate the effects of multiple-dose administration of TBAJ-876 on the safety and tolerability of an antiretroviral regimen.

3. STUDY DESIGN

This is a phase 1, open-label, single-center, drug-drug interaction study. Two sequential study phases are planned. The performance of the second phase is conditional on the outcome of the first. The planned enrollment to the first phase of the study is 28 healthy males and females between 18 and 55 years of age. This phase of the study will last 34 days for each subject, from Check-in on Day −1 through completion of the clinical procedures on Day 25 and a follow-up phone call on Day 32.

Subjects will be screened for eligibility to participate in the study up to 21 days prior to admission to the study center on Day −1. Eligible subjects will be admitted to the study center on Day −1 and will be confined there under observation until they are discharged on Day 25. Following discharge, subjects will receive a follow-up phone call on Day 32.

All subjects will receive treatment with single daily doses according to the following schedule:

Day 1	Midazolam oral syrup, 2 mg	Fasted
Day 2	Digoxin tablet, 0.25 mg	Fasted
Day 6 – 13	TBAJ-876 oral suspension, 200 mg	Fed
Day 14 – 19	TBAJ-876 oral suspension, 165 mg	Fed
Day 20	Midazolam oral syrup, 2 mg; TBAJ-876 oral suspension, 200 mg	Fasted
Day 21	Digoxin tablet, 0.25 mg; TBAJ-876 oral suspension, 200 mg	Fasted
Day 22 – 24	TBAJ-876 oral suspension, 150 mg	Fed

The following safety assessments will be performed at scheduled time points throughout the study:

Physical examinations	Screening and Days −1, 2, 3, 4, 5, and 25, or early withdrawal.
Vital signs (blood pressure, heart rate [pulse], temperature, and respiration rate, pulse oximetry)	Screening and Days −1 Pre-dose and 0.5, 1, 2, 6, and 12 hours post-dose on Days 1, 2, 6, 20, and 21 6 hours post-dose on Days 7 through 19 Days 24 and 25, or early withdrawal.
Electrocardiogram (ECG)	Once at Screening and Days −1, 3, 7, 20, 22, and 25, or upon early withdrawal; also on Days 2 and 21, pre-dose and 0.5, 1, 2, 6, and 12 hours post-dose.
Adverse events (AEs)	Ongoing collection throughout the study period.
Clinical laboratory tests (hematology, serum chemistry, coagulation, and urinalysis)	Screening and Days −1, 2, 3, 7, 20, 21, 22, and 25, or upon early withdrawal.

Blood samples will be taken according to the following schedule for determination of plasma concentrations of the corresponding analytes:

Day 1	Pre-dose, 0.25, 0.5, 1, 2, 3, 4, 6, 8, 12, 24 hours	Midazolam and its metabolite 1-hydroxymidazolam
Day 2	Pre-dose, 0.5, 1, 2, 3, 4, 6, 8, 12, 24, 48, 72, 96 hours	Digoxin
Day 17	Pre-dose, 0.5, 3, 4, 5, 6, 7, 8, 12, 16, 20, 24 hours	TBAJ-876 and its metabolites M2 and M3
Day 20	Pre-dose, 0.25, 0.5, 1, 2, 3, 4, 6, 8, 12, 24 hours	Midazolam and its metabolite 1-hydroxymidazolam
Day 21	Pre-dose, 0.5, 1, 2, 3, 4, 6, 8, 12, 24, 48, 72, 96 hours	Digoxin

4. HARDWARE AND SOFTWARE

Statistical analysis will be performed following TKL standard operating procedures (SOPs) and on the TKL computer network. All statistical analyses will be performed using SAS Version 9.4 or higher with program code prepared specifically for the project by qualified TKL statisticians and SAS programmers.

The SAS programs will generate rich-text-formatted (RTF) output with the "RTF" extension using the SAS Output Delivery System (ODS). The summary tables and listings will be formatted using the Times New Roman font. The RTF output is included in report documents prepared with Microsoft Word and converted to PDF format without typographical change.

Study data tabulation model (SDTM) data sets and required analysis data model (ADaM) data sets will be created and taken as input to validated SAS programs to generate the report-ready tables, listings, and figures. Each output display will show the names of the data sets and SAS program used to produce it. Upon completion of the study report, the data sets will be provided to the sponsor as SAS XPT transport files with define.xml files including details of all derivations and imputations used.

5. STATISTICAL DATA REVIEW

Data verification activities to be performed prior to delivery of the SAS data sets to the project statistician are described in the approved Data Management Plan (DMP). After completion of the data verification activities, the SAS data sets will be reviewed by the project statistician along with documentation of any unresolved queries and data conventions applied that are not fully explained in the data or in the DMP. The project statistician will perform completeness and self-consistency checks of the study data. These checks will be selected to ensure the self-consistency of dates and events in the subject record, the consistency of all reported data values with expected ranges, and, if not within range, the presence in the subject record of explanatory comments or other corroborative data. Overall, each subject's record in the study database must convey a full but concise description of the subject's experience with respect to protocol-specific events. Questions will be issued to the Data Manager and resolved before closure of the database.

6. DATABASE CLOSURE

After completion of all data review procedures, validation of the project database (ie, all those activities and operations designed and performed to ensure that the database is a complete and accurate representation of protocol-specific events), and approval of the data review document by the study sponsor, the clinical database will be closed (ie, "locked"). Any change to the clinical database after this time will require written authorization, with explanation, by the Sponsor and the Biostatistician, in conformance with TKL SOPs.

7. SAMPLE SIZE DETERMINATION

The study sample size for this Phase 1 study is based on statistical power calculations as detailed in the study protocol, section 10.2.

8. HANDLING OF MISSING DATA

In this study, there will be no imputations of missing data points. All data will be reported and analyzed as observed values only.

9. ANALYSIS POPULATIONS

The analysis populations will be determined according to available data. Relevant data for all subjects enrolled to the study will be reported. The Safety population for analysis of adverse events, clinical laboratory test results, and other safety-related variables will include all

subjects who received treatment with any one of the study drugs. The Pharmacokinetics (PK) population for analysis of plasma concentration data and pharmacokinetic parameters will include all subjects presenting data sufficient to calculate the analysis parameter. In case a subject cannot be included in a particular analysis, the rationale for the omission of that subject will be fully explained in the study report.

10. STATISTICAL EVALUATION

10.1 Subject Disposition

Subject disposition will be summarized by showing the number of subjects screened, and the number and percent of screen failures and enrolled subjects; the number and percent of subjects completed and discontinued, along with the primary reason for discontinuation. By-subject listings will include date of informed consent, date of screening, date-time of enrollment, date of last visit, date of last contact, and reason for discontinuation. Individual subject data for any protocol deviations will also be presented in a by-subject listing.

10.2 Demographic and Other Covariates

Subject age, height, weight, and BMI will be summarized for the Safety population as mean, standard deviation, median, minimum, and maximum. Sex, race, and ethnicity will be summarized as number and percent of subjects in each category. Subject listings will include age, sex, race, ethnicity, weight, height, and body mass index.

Prior (prior to the start of treatment) medication use and concomitant (after the start of treatment) medication use will be summarized separately. If the end date of a prior medication occurs after treatment starts, then the medication will be reported in both the prior and concomitant tables and listings. These tables will present the number and percentage of subjects for each medication. Medication terms will be coded and classified according to the WHO Drug Dictionary, Version B3 (March 2022).

Data listings will also be provided to show medical history, childbearing potential and pregnancy test results, and general investigator comments.

10.3 Pharmacokinetics Evaluations

Plasma concentrations will be summarized at each time point for each measured analyte as mean, standard deviation, median, coefficient of variation, standard error of the mean, minimum and maximum. Individual subject data will be plotted against time post-dose on linear and log-linear axes. Day 1 and Day 20 midazolam concentrations, and Day 2 and

Day 21 digoxin concentrations, will be overlayed on a single set of axes to permit visual comparison. Similar displays will be constructed for the mean concentrations of each analyte over time post-dose.

The following pharmacokinetics parameters will be determined for each subject and study day for midazolam, 1-hydroxymidazolam, and digoxin:

- $AUC_{0\text{-last}}$, the area under the curve of plasma concentration vs time post-dose, approximated trapezoidally, from 0 to the time of last measurable concentration;
- C_{max}, the maximum observed concentration;
- t_{max}, the time post-dose of the maximum observed concentration.

The individual subject plots of each analyte concentration vs time will be inspected visually to identify log-linear terminal segments corresponding to an exponential elimination phase. If at least 3 observations are presented along what appears to be a terminal elimination phase, then the elimination rate constant will be estimated using a linear regression fit to the plot of log concentration vs time during this phase. The value of the elimination rate constant, k_{el}, is the absolute magnitude of the estimated slope.

Using the following SAS code,

```
proc                    reg                    outest=KOUT;
model              LOGCONC              =              TIME;
quit;
```

the value of k_{el} is computed as ABS(TIME) in the dataset KOUT, and the value of the elimination half-life, $t_{1/2}$, is LOG(2)/KEL.

When k_{el} and $t_{1/2}$ are estimated, the following additional parameters will be computed:

- $AUC_{0\text{-inf}}$, the area under the curve of plasma concentration vs time post-dose, extrapolated to infinite time, calculated as $AUC_{0\text{-last}} + C_{last}/k_{el}$;
- CL/F, total apparent drug clearance rate, defined as oral dose / $AUC_{0\text{-inf}}$; (Note that when oral dose is provided in units of mg, the AUC must be converted to units of mg.hr/L.)
- V_Z/F, apparent volume of distribution, defined as CL/F divided by k_{el}.

In addition to mean, standard deviation, median, minimum, and maximum, the AUC parameters and Cmax will be summarized by treatment group as geometric mean and coefficient of variation (ie, 100*SQRT(EXP(VAR) - 1) with VAR= the variance of the log-

transformed values). Elimination rate constant, half-life, and t_{max} will be summarized as median, minimum, and maximum. Drug clearance and volume of distribution will be summarized as mean, standard deviation, minimum, and maximum.

To compare pharmacokinetic parameters of the interaction products with TBAJ-876 versus alone, analyses of variance (ANOVA) will be performed using SAS PROC MIXED. The model will include subject as a random effect and treatment (with TBAJ-876 versus alone) as a fixed effect. Geometric least-squares mean values and 95% confidence intervals (CIs) will be tabulated for $AUC_{0\text{-}inf}$ and C_{max}. The ratio of geometric means (GMR) will be computed comparing co-administration with TBAJ-876 versus alone, along with the 90% 2-sided CI. The test drug TBAJ-876 will be considered a moderate inducer of CYP3A4 if the estimated GMR of midazolam $AUC_{0\text{-}inf}$ is less than 0.50. It will be considered a moderate inducer of P-glycoprotein if the estimated GMR of digoxin $AUC_{0\text{-}inf}$ is less than 0.50. If the estimated GMR of digoxin $AUC_{0\text{-}inf}$ is 2.0 or greater, then TBAJ-876 will be considered a moderate inhibitor of P-glycoprotein. These results will be used to decide whether to conduct the second phase of the study.

The following pharmacokinetics parameters will be determined for each subject for TBAJ-876 and its metabolites M2 and M3 on Day 17:

- $AUC_{0\text{-}24}$, the area under the curve of plasma concentration vs time post-dose, approximated trapezoidally, from 0 to 24 hours post-dose;
- C_{max}, the maximum observed concentration;
- t_{max}, the time post-dose of the maximum observed concentration.
- C_{trough}, the observed pre-dose concentration.

The sum of $AUC_{0\text{-}24}$ for TBAJ-876 and its M3 metabolite will also be summarized. In addition to mean, standard deviation, median, minimum, and maximum, the AUC parameters and Cmax will be summarized by treatment group as geometric mean and coefficient of variation (ie, 100*SQRT(EXP(VAR) - 1) with VAR= the variance of the log-transformed values). The summary of t_{max} will be as median, minimum, and maximum. Trough concentration will be summarized as mean, standard deviation, minimum, and maximum.

10.4 Safety Evaluations

All safety analysis will be performed using the Safety analysis population and will be presented by group Adverse event terms will be coded using the MedDRA version 25 (2022) dictionary. All AEs will be presented in a by-subject listing, detailing the verbatim term given by the investigator, the preferred term (PT), system organ class (SOC), onset date and time, end date

and time, severity, outcome, relationship to study drug, action taken with study drug, other action taken, seriousness and criteria for seriousness.

All safety and tolerability data collected in the study will be listed by participant. The continuous variables will be summarized using number of eligible subjects (N), mean, standard deviation, median, minimum, and maximum. Frequency counts and percentages will be reported for categorical data.

A treatment emergent adverse event is defined as an AE beginning on or after Day 1 of the study. The number of events and the number and percent of subjects experiencing adverse events will be presented for all treatment-emergent adverse events (TEAE), all treatment-related TEAEs, all severe TEAEs (Grades 3 and 4), and all TEAEs leading to study discontinuation. Number and percent of subjects with TEAEs will also be shown by SOC and PT.

Vital signs, ECG measurements, and clinical laboratory test results (including hematology, serum chemistry, coagulation, and urinalysis) will be summarized at each time point as mean, standard deviation, median, minimum, and maximum. The investigator's assessments of ECG as normal or abnormal will be summarized as number and percentage of subjects. Also, the presence of heart murmur at each time point will be summarized as number and percentage of subjects. Every cardiovascular safety incident will be listed by timepoint with accompanying symptoms and with BP and HR measurements.

The results of all safety-related data, including physical examinations findings, vital signs, ECG assessments, and clinical laboratory test results, will be presented in by-subject listings.

11. CHANGES FROM THE PROTOCOL AND PLANNED ANALYSES

All exceptions to the planned analyses as described herein will be clearly indicated and explained in the study report.

12. HEADINGS

Each page of the analysis will show the sponsor's name, the investigational product, and the protocol number. Report tables will be embedded in the MS Word report document from SAS program output without change. The footer of each table will show the name of the SAS program module which generated it, the names of all data sets providing input data in the program and the date and time the table was generated.

13. ARCHIVING AND RETENTION OF DOCUMENTS

After finalization of the analysis, the following will be archived at TKL Research, Inc. and/or with the study sponsor:

- SAP and any amendments
- DMP and Database Specification
- All SAS code used in the project for statistical analysis, report tables generation, and analysis data set creation
- Tables, listings and figures as included in the clinical study report
- SDTM and ADaM datasets
- Relevant correspondence
- Any other pertinent study document (ie, study protocol, investigator's brochure, correspondence, study report, etc.).

15. OUTLINE OF PROPOSED TABLES, FIGURES AND LISTINGS

Summary Tables

14.1.1	Summary of Subject Disposition
14.1.2	Summary of Subject Demographics and Baseline Variables
14.1.3	Summary of Prior Medications
14.1.4	Summary of Concomitant Medications
14.2.1.1	Summary of Plasma Midazolam Concentrations (ng/mL)
14.2.1.2	Summary of Plasma Digoxin Concentrations (ng/mL)
14.2.1.3	Summary of Day 17 Plasma TBAJ-876 Concentrations (ng/mL)
14.2.2	Summary of Drug-Drug Interaction
14.2.3.1	Summary of Midazolam Pharmacokinetic Parameters
14.2.3.2	Summary of Digoxin Pharmacokinetic Parameters
14.2.3.3	Summary of Day 17 TBAJ-876 Pharmacokinetic Parameters
14.3.1	Summary of Treatment-Emergent Adverse Events
14.3.2	Summary of Physical Examinations Findings
14.3.3	Summary of Vital Signs
14.3.4	Summary of ECG Findings
14.3.5.1	Summary of Clinical Laboratory Test Results, Hematology and Coagulation
14.3.5.2	Summary of Clinical Laboratory Test Results, Differential Blood Count
14.3.5.3	Summary of Clinical Laboratory Test Results, Electrolytes and Renal Function
14.3.5.4	Summary of Clinical Laboratory Test Results, Liver Function
14.3.5.5	Summary of Clinical Laboratory Test Results, Other Serum Chemistry
14.3.5.6	Summary of Clinical Laboratory Test Results, Urinalysis, Part 1
14.3.5.7	Summary of Clinical Laboratory Test Results, Urinalysis, Part 2

Figures

Listings

16.2.5.1	Plasma Midazolam Concentrations
16.2.5.2	Plasma 1-Hydroxymidazolam Concentrations
16.2.5.3	Plasma Digoxin Concentrations
16.2.5.4	Plasma TBAJ-876 Concentrations
16.2.5.5	Plasma M2 Concentrations
16.2.5.6	Plasma M3 Concentrations
16.2.6.1	Midazolam Pharmacokinetic Parameters
16.2.6.2	1-Hydroxymidazolam Pharmacokinetic Parameters
16.2.6.3	Digoxin Pharmacokinetic Parameters
16.2.6.4	TBAJ-876 Dosing
16.2.6.5	TBAJ-876 Day 17 Pharmacokinetic Parameters
16.2.7.1	Adverse Events
16.2.7.2	Serious Adverse Events and Adverse Events Leading to Study Discontinuation
16.2.7.3	Cardiovascular Adverse Events
16.2.8.1	Physical Examinations
16.2.8.2	Vital Signs Measurements
16.2.8.3	Electrocardiogram (ECG) Results
16.2.8.4.1	Clinical Laboratory Test Results, Hematology and Coagulation
16.2.8.4.2	Clinical Laboratory Test Results, Differential Blood Count
16.2.8.4.3	Clinical Laboratory Test Results, Electrolytes and Renal Function
16.2.8.4.4	Clinical Laboratory Test Results, Liver Function
16.2.8.4.5	Clinical Laboratory Test Results, Other Serum Chemistry
16.2.8.4.6	Clinical Laboratory Test Results, Urinalysis, Part 1
16.2.8.4.7	Clinical Laboratory Test Results, Urinalysis, Part 2
16.2.8.4.8	Laboratory Values Outside of Normal Range
16.2.8.5	Childbearing Potential and Serum Pregnancy Test Results
16.2.9	General Comments

Table 14.1.1: Summary of Subject Disposition

Number of Subjects Screened	xx
n (%) Enrolled	xx (xx.x)
n (%) Screen Failure	xx (xx.x)
Number Enrolled	xx
n (%) Completed Study	xx (xx.x)
n (%) Discontinued Study	xx (xx.x)
n (%) Adverse Event/Serious Adverse Event	xx (xx.x)
n (%) Important Protocol Deviation (eg, non-compliance)	xx (xx.x)
n (%) Investigator Judgment	xx (xx.x)
n (%) Lost to Follow-up	xx (xx.x)
n (%) xxxxxxxxxxx	xx (xx.x)

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

[Programming Note: List reasons for discontinuation in descending order of frequency. Omit rows with zero counts.]

Table 14.1.2: Summary of Subject Demographics and Baseline Variables
Safety population (N=xx)

	Parameter	Statistic	
	Age	Mean (SD)	xxx (xx.x)
		Median	xxx
		Minimum, maximum	xxx, xxx
	Sex	n (%) Male	x (xx.x)
		n (%) Female	x (xx.x)
	Race	n (%) White	x (xx.x)
		n (%) Black or African American	x (xx.x)
		n (%) Asian	x (xx.x)
		n (%) American Indian or Alaska Native	x (xx.x)
		n (%) Native Hawaiian or Other Pacific Islander	x (xx.x)
	Ethnicity	n (%) Hispanic or Latino	x (xx.x)
		n (%) Not Hispanic or Latino	x (xx.x)

Note: Subjects could select more than one race and are counted in each race selected. SD=Standard deviation.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

[Programming Note: Omit rows with zero counts.]

Table 14.1.2: Summary of Subject Demographics and Baseline Variables
Safety population (N=xx)

	Parameter	Statistic	
	Height (cm)	Mean (SD)	xxx (xx.x)
		Median	xxx
		Minimum, maximum	xxx, xxx
	Weight (kg)	Mean (SD)	xx.x (xx.x)
		Median	xx.x
		Minimum, maximum	xx.x, xx.x
	BMI (kg/m^2)	Mean (SD)	xx.x (xx.x)
		Median	xx.x
		Minimum, maximum	xx.x, xx.x

SD=Standard deviation.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Table 14.1.3: Summary of Prior Medications
Safety population (N=xx)

Number (%) of Subjects with Any Prior Medication	xx (xx.x)
[ATC2]	xx (xx.x)
[WHO Preferred Name 1]	xx (xx.x)
[WHO Preferred Name 2]	xx (xx.x)
[ATC2]	xx (xx.x)
[WHO Preferred Name 1]	xx (xx.x)
[WHO Preferred Name 2]	xx (xx.x)
[ATC2]	xx (xx.x)
[WHO Preferred Name 1]	xx (xx.x)
[WHO Preferred Name 2]	xx (xx.x)

Note: Medications that were continued into the study period are summarized as both prior and concomitant.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

[Programming Note: List ATC2 classes and preferred names in descending order of frequency]

Table 14.1.4: Summary of Concomitant Medications
Safety population (N=xx)

Number (%) of Subjects with Any Concomitant Medication	xx (xx.x)
[ATC2]	xx (xx.x)
[WHO Preferred Name 1]	xx (xx.x)
[WHO Preferred Name 2]	xx (xx.x)
[ATC2]	xx (xx.x)
[WHO Preferred Name 1]	xx (xx.x)
[WHO Preferred Name 2]	xx (xx.x)
[ATC2]	xx (xx.x)
[WHO Preferred Name 1]	xx (xx.x)
[WHO Preferred Name 2]	xx (xx.x)

Note: Medications that were continued into the study period are summarized as both prior and concomitant.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

[Programming Note: List ATC2 classes and preferred names in descending order of frequency]

Table 14.2.1.1: Summary of Plasma Midazolam Concentrations (ng/mL)
PK Population

Time Point	Statistic	Midazolam		1-Hydroxymidazolam	
		Alone	**With TBAJ-876**	**Alone**	**With TBAJ-876**
[Pre-dose, 15 mins, 30 mins, 1 hr, 2 hrs, 3 hrs, 4 hrs, 6 hrs, 8 hrs, 12 hrs, 24 hrs]	n	xx	xx	xx	x
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx	xxx	xxx
	Geometric mean	xxx	xxx	xxx	xxx
	CV (%)	xx.x	xx.x	xx.x	xx.x
	Minimum, maximum	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx

SD=Standard deviation, CV=Coefficient of variation.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Table 14.2.1.2: Summary of Plasma Digoxin Concentrations (ng/mL)
PK Population

		Digoxin	
Time Point	**Statistic**	**Alone**	**With TBAJ-876**
[Pre-dose, 30 mins, 1 hr, 2 hrs, 3 hrs, 4 hrs, 6 hrs, 8 hrs, 12 hrs, 24 hrs, 48 hrs, 72 hrs, 96 hrs]	n	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx
	Geometric mean	xxx	xxx
	CV (%)	xx.x	xx.x
	Minimum, maximum	xxx, xxx	xxx, xxx

SD=Standard deviation, CV=Coefficient of variation.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Table 14.2.1.3: Summary of Day 17 Plasma TBAJ-876 Concentrations (ng/mL)
PK Population

Time Point	Statistic	TBAJ-876	M2	M3
[Pre-dose, 30 mins, 3 hrs, 4 hrs, 5 hrs, 6 hrs, 7 hrs, 8 hrs, 12 hrs, 16 hrs, 20 hrs, 24 hrs]	n	xx	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx	xxx
	Geometric mean	xxx	xxx	xxx
	CV (%)	xx.x	xx.x	xx.x
	Minimum, maximum	xxx, xxx	xxx, xxx	xxx, xxx

SD=Standard deviation, CV=Coefficient of variation.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Table 14.2.2: Summary of Drug-Drug Interaction
PK Population

	Midazolam	**Digoxin**
$AUC_{0\text{-}inf}$ (ng.hr/mL)	N=xx	N=xx
Least-squares geometric mean (with TBAJ-876 [T])	xxx	xxx
Least-squares geometric mean (alone [R])	xxx	xxx
Ratio of geometric means (T/R)	x.xxx	x.xxx
90% 2-sided confidence interval	[x.xxx, x.xxx]	[x.xxx, x.xxx]
C_{max} (ng/mL)	N=xx	N=xx
Least-squares geometric mean (with TBAJ-876 [T])	xxx	xxx
Least-squares geometric mean (alone [R])	xxx	xxx
Ratio of geometric means (T/R)	x.xxx	x.xxx
90% 2-sided confidence interval	[x.xxx, x.xxx]	[x.xxx, x.xxx]

Note: All estimates are of least squares means using the mixed linear model analysis of variance with random effects of subject and fixed effects of treatment.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Table 14.2.3.1: Summary of Midazolam Pharmacokinetic Parameters
PK Population

Parameter	Statistic	Midazolam		1-Hydroxymidazolam	
		Alone	**With TBAJ-876**	**Alone**	**With TBAJ-876**
$AUC_{0\text{-last}}$ (ng.hr/mL)	n	xx	xx	xx	x
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx	xxx	xxx
	Geometric mean	xxx	xxx	xxx	xxx
	CV (%)	xx.x	xx.x	xx.x	xx.x
	Minimum, maximum	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
$AUC_{0\text{-inf}}$ (ng.hr/mL)	n	xx	xx	xx	x
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx	xxx	xxx
	Geometric mean	xxx	xxx	xxx	xxx
	CV (%)	xx.x	xx.x	xx.x	xx.x
	Minimum, maximum	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
C_{max} (ng/mL)	n	xx	xx	xx	x
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx	xxx	xxx
	Geometric mean	xxx	xxx	xxx	xxx
	CV (%)	xx.x	xx.x	xx.x	xx.x
	Minimum, maximum	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx

SD=Standard deviation, CV=Coefficient of variation.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Table 14.2.3.1: Summary of Midazolam Pharmacokinetic Parameters
PK Population

		Midazolam		1-Hydroxymidazolam	
Parameter	**Statistic**	**Alone**	**With TBAJ-876**	**Alone**	**With TBAJ-876**
T_{max} (hr)	n	xx	xx	xx	x
	Median	xxx	xxx	xxx	xxx
	Minimum, maximum	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
k_{el} (/hr)	n	xx	xx	xx	x
	Median	xxx	xxx	xxx	xxx
	Minimum, maximum	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
$t_{1/2}$ (hr)	n	xx	xx	xx	x
	Median	xxx	xxx	xxx	xxx
	Minimum, maximum	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
CL/F (L/hr)	n	xx	xx	xx	x
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx	xxx	xxx
	Minimum, maximum	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
V_Z/F (L)	n	xx	xx	xx	x
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx	xxx	xxx
	Minimum, maximum	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx

SD=Standard deviation, CV=Coefficient of variation.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Table 14.2.3.2: Summary of Digoxin Pharmacokinetic Parameters
PK Population

Parameter	Statistic	Digoxin	
		Alone	**With TBAJ-876**
$AUC_{0\text{-last}}$ (ng.hr/mL)	n	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx
	Geometric mean	xxx	xxx
	CV (%)	xx.x	xx.x
	Minimum, maximum	xxx, xxx	xxx, xxx
$AUC_{0\text{-inf}}$ (ng.hr/mL)	n	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx
	Geometric mean	xxx	xxx
	CV (%)	xx.x	xx.x
	Minimum, maximum	xxx, xxx	xxx, xxx
C_{max} (ng/mL)	n	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx
	Geometric mean	xxx	xxx
	CV (%)	xx.x	xx.x
	Minimum, maximum	xxx, xxx	xxx, xxx

SD=Standard deviation, CV=Coefficient of variation.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Table 14.2.3.2: Summary of Digoxin Pharmacokinetic Parameters
PK Population

Parameter	Statistic	Digoxin	
		Alone	**With TBAJ-876**
T_{max} (hr)	n	xx	xx
	Median	xxx	xxx
	Minimum, maximum	xxx, xxx	xxx, xxx
k_{el} (/hr)	n	xx	xx
	Median	xxx	xxx
	Minimum, maximum	xxx, xxx	xxx, xxx
$t_{1/2}$ (hr)	n	xx	xx
	Median	xxx	xxx
	Minimum, maximum	xxx, xxx	xxx, xxx
CL/F (L/hr)	n	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx
	Minimum, maximum	xxx, xxx	xxx, xxx
V_Z/F (L)	n	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx
	Minimum, maximum	xxx, xxx	xxx, xxx

SD=Standard deviation, CV=Coefficient of variation.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

TB Alliance
Protocol Number: TBAJ-876-CL002

Table 14.2.3.3: Summary of Day 17 TBAJ-876 Pharmacokinetic Parameters
PK Population

Parameter		TBAJ-876	M2	M3	Sum of TBAJ-876 and M3
AUC_{0-24} (ng.hr/mL)	n	xx	xx	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx	xxx	xxx
	Geometric mean	xxx	xxx	xxx	xxx
	CV (%)	xx.x	xx.x	xx.x	xx.x
	Minimum, maximum	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
C_{max} (ng/mL)	n	xx	xx	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx	xxx	xxx
	Geometric mean	xxx	xxx	xxx	xxx
	CV (%)	xx.x	xx.x	xx.x	xx.x
	Minimum, maximum	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
t_{max} (hr)	n	xx	xx	xx	xx
	Median	xxx	xxx	xxx	xxx
	Minimum, maximum	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
C_{trough} (ng/mL)	n	xx	xx	xx	xx
	Mean (SD)	xxx	xxx	xxx	xxx
	Minimum, maximum	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx

SD=Standard deviation.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Table 14.3.1: Summary of Treatment-Emergent Adverse Events
Safety Population (N=xx)

All TEAEs	Number of events	xx
	n (%) of subjects	xx (xx.x)
Treatment-related TEAEs	Number of events	xx
	n (%) of subjects	xx (xx.x)
Severe TEAEs	Number of events	xx
	n (%) of subjects	xx (xx.x)
TEAEs leading to study discontinuation	Number of events	xx
	n (%) of subjects	xx (xx.x)
[SOC1]	n (%) of subjects	xx (xx.x)
[PT1]		xx (xx.x)
[PT2]		xx (xx.x)
[PT3]		xx (xx.x)
[SOC2]		xx (xx.x)
[PT1]		xx (xx.x)
[PT2]		xx (xx.x)

TEAE=Treatment-emergent adverse event (with onset on or after Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

TB Alliance
Protocol Number: TBAJ-876-CL002

Table 14.3.2: Summary of Physical Examinations Findings
Safety Population

		n(%) Abnormal									Presence of Heart Murmur
Time Point	**N**	**HEENT**	**Neck**	**Heart**	**Resp**	**Abd**	**MS**	**Neur**	**Skin**	**Other**	
Screening	xx	x (xx.x)	0	0	0	0	x (xx.x)	0	0	0	0
Day -1	xx	0	0	0	0	0	0	0	0	0	0
Day 2	xx	0	0	0	0	0	0	0	0	0	0
Day 3	xx	0	x (xx.x)	0	0	0	0	0	0	0	0
Day 4	xx	0	0	0	0	0	0	0	0	0	x (xx.x)
Day 5	xx	0	0	0	0	0	0	0	x (xx.x)	0	0
Day 25/ET	xx	0	0	0	0	0	0	0	0	0	0

Resp=Respiratory, Abd=Abdomen, MS=Musculoskeletal, Neur=Neurological status.

Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

[Note: Show 0 without percentage as shown.]

Table 14.3.3: Summary of Vital Signs
Safety Population

Time Point		Supine Systolic BP (mmHg)	Supine Diastolic BP (mmHg)	Supine Heart Rate (bpm)	Temp (C)	Resp Rate (bpm)	Pulse Oximetry (%)	Supine Systolic BP (mmHg)	Supine Diastolic BP (mmHg)	Supine Heart Rate (bpm)
Screening	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx	xxx	xx.x	xx.x	xx.x	xxx	xxx	xxx
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xxx, xxx	xxx, xxx	xxx, xxx
Day -1	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx	xxx	xx.x	xx.x	xx.x	xxx	xxx	xxx
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xxx, xxx	xxx, xxx	xxx, xxx
Day 1, Pre-dose	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx	xxx	xx.x	xx.x	xx.x	xxx	xxx	xxx
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xxx, xxx	xxx, xxx	xxx, xxx
Day 1, 0.5 hrs	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Median	xxx	xxx	xxx	xx.x	xx.x	xx.x	xxx	xxx	xxx
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xxx, xxx	xxx, xxx	xxx, xxx
etc.										

Table 14.3.4.1: Summary of ECG Findings
Safety Population

Time Point		HR (bpm)	PR (msec)	QRS (msec)	QT (msec)	QTcF (msec)	Investigator's Assessment	
Screening	n	xx	xx	xx	xx	xx		
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xx.x (xx.x)	xx.x (xx.x)	Normal, n(%)	xx (xx.x)
	Median	xxx	xxx	xxx	xx.x	xx.x	Abnormal, n(%)	xx (xx.x)
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xx.x, xx.x	xx.x, xx.x		
Day -1	n	xx	xx	xx	xx	xx		
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xx.x (xx.x)	xx.x (xx.x)	Normal, n(%)	xx (xx.x)
	Median	xxx	xxx	xxx	xx.x	xx.x	Abnormal, n(%)	xx (xx.x)
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xx.x, xx.x	xx.x, xx.x		
Day 2, Pre-dose	n	xx	xx	xx	xx	xx		
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xx.x (xx.x)	xx.x (xx.x)	Normal, n(%)	xx (xx.x)
	Median	xxx	xxx	xxx	xx.x	xx.x	Abnormal, n(%)	xx (xx.x)
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xx.x, xx.x	xx.x, xx.x		
Day 2, 0.5 hrs	n	xx	xx	xx	xx	xx		
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xx.x (xx.x)	xx.x (xx.x)	Normal, n(%)	xx (xx.x)
	Median	xxx	xxx	xxx	xx.x	xx.x	Abnormal, n(%)	xx (xx.x)
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xx.x, xx.x	xx.x, xx.x		
etc.								

Table 14.3.4.2: Summary of 12-Lead ECG Numeric Results
Absolute Values and Change from Baseline by Treatment and Time Point
Safety Population

	Group 1 (N=XX)	**Group 2 (N=XX)**	**Overall (N=XX)**
[Tests Name (Units)]			
Baseline			
N	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX
Day 1 Post-Dose [2]			
N	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX
Change from Baseline			
N	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX

<Continue for all other applicable study days>

Note: Baseline is the last available measurement prior to the first dose of the study drug on Day 1.

Generated on` XX/XX/XX:XXXX by XXX / Uses: XXXX / Reference: Data Listing XXXX

[Programming note: Summarize all ECG tests with continuous results, including ventricular rate, PR, QRS, QT, QTcF intervals. Page break between ECG tests.]

Table 14.3.4.3: Summary of 12-Lead ECG Categorical Analysis
QTcF
Safety Population

	Group 1 (N=XX)	**Group 2 (N=XX)**	**Overall (N=XX)**
QTcF (msec)			
Absolute Values [1]			
> 450	XX (XX.X)	XX (XX.X)	XX (XX.X)
> 480	XX (XX.X)	XX (XX.X)	XX (XX.X)
> 500	XX (XX.X)	XX (XX.X)	XX (XX.X)
Change from baseline [2]			
> 30	XX (XX.X)	XX (XX.X)	XX (XX.X)
> 60	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Baseline is the last available measurement prior to the first dose of the study drug on Day 1.

[1] Subjects with QTcF absolute values > (450, 480 and 500 msec) at any post dosing time point are included.
[2] Subjects with QTcF change from baseline values > (30 and 60 msec) at any post dosing time point are included.
<Programming Note: Additional QTcF value categories may be added to aid data interpretation.

Generated on XX/XX/XX:XXXX by XXX / Uses: XXXX / Reference: Data Listing XXXX

TB Alliance
Protocol Number: TBAJ-876-CL002

Table 14.3.5.1: Summary of Clinical Laboratory Test Results, Hematology and Coagulation
Safety Population

Time Point		HCT (ratio)	HGB (g/L)	RBC (10^12/L)	WBC (10^9/L)	PLAT (10^9/L)	RETI (ratio)	aPTT2 (sec)	PT2 (sec)
Screening	n	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	x.xx (x.xx)	x.x (x.x)	xxx (xx.x)	.xxx (.xxx)	xx (xx.x)	xx (xx.x)
	Median	xxx	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Min, Max	xxx, xxx	xxx, xxx	x.xx, x.xx	x.x, x.x	xxx, xxx	.xxx, .xxx	xx, xx	xx, xx
Day -1	n	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	x.xx (x.xx)	x.x (x.x)	xxx (xx.x)	.xxx (.xxx)	xx (xx.x)	xx (xx.x)
	Median	xxx	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Min, Max	xxx, xxx	xxx, xxx	x.xx, x.xx	x.x, x.x	xxx, xxx	.xxx, .xxx	xx, xx	xx, xx
Day 2	n	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	x.xx (x.xx)	x.x (x.x)	xxx (xx.x)	.xxx (.xxx)	xx (xx.x)	xx (xx.x)
	Median	xxx	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Min, Max	xxx, xxx	xxx, xxx	x.xx, x.xx	x.x, x.x	xxx, xxx	.xxx, .xxx	xx, xx	xx, xx
Day 3	n	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xxx (xx.x)	xxx (xx.x)	x.xx (x.xx)	x.x (x.x)	xxx (xx.x)	.xxx (.xxx)	xx (xx.x)	xx (xx.x)
	Median	xxx	xxx	x.xx	x.x	xxx	.xxx	xx	xx
etc	Min, Max	xxx, xxx	xxx, xxx	x.xx, x.xx	x.x, x.x	xxx, xxx	.xxx, .xxx	xx, xx	xx, xx

HCT = Hematocrit; HGB = Hemoglobin; RBC = Erythrocytes; WBC=Leukocytes; PLAT = Platelets, RETI=Reticulocytes, aPTT2=Activated partial thromboplastin time, PT2=Prothrombin time.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Table 14.3.5.2: Summary of Clinical Laboratory Test Results, Differential Blood Count
Safety Population

		NEUT		LYM		MONO		EOS		BASO	
Time Point		**(10^9/L)**	**(Ratio)**	**(10^9/L)**	**(Ratio)**	**(10^9/L)**	**(Ratio)**	**(10^9/L)**	**(Ratio)**	**(10^9/L)**	**(Ratio)**
Screening	n	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)
	Median	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx
	Min, Max	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx
Day -1	n	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)
	Median	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx
	Min, Max	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx
Day 2	n	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)
	Median	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx
	Min, Max	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx
	n	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Day 3	Mean (SD)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	x.xx (x.xx)
	Median	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx
etc	Min, Max	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx	x.x, x.x	x.xx, x.xx

NEUT = Neutrophils; LYM = Lymphocytes; MONO = Monocytes; EOS = Eosinophils; BASO = Basophils

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Table 14.3.5.3: Summary of Clinical Laboratory Test Results, Electrolytes and Renal Function
Safety Population

Time Point		SODIUM (mmol/L)	K (mmol/L)	CL (mmol/L)	BICARB (mmol/L)	CA (mmol/L)	MG (mmol/L)	UREAN (mmol/L)	CREAT (umol/L)
Screening	n	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xxx (xx.x)	x.x (x.x)	xxx (xx.x)	xx (xx.x)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	xx (xx.x)
	Median	xxx	x.x	xxx	xx	x.x	x.xx	x.x	xx
	Min, Max	xxx, xxx	x.x, x.x	xxx, xxx	xx, xx	x.x, x.x	x.xx, x.xx	x.x, x.x	xx, xx
Day -1	n	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xxx (xx.x)	x.x (x.x)	xxx (xx.x)	xx (xx.x)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	xx (xx.x)
	Median	xxx	x.x	xxx	xx	x.x	x.xx	x.x	xx
	Min, Max	xxx, xxx	x.x, x.x	xxx, xxx	xx, xx	x.x, x.x	x.xx, x.xx	x.x, x.x	xx, xx
Day 2	n	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xxx (xx.x)	x.x (x.x)	xxx (xx.x)	xx (xx.x)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	xx (xx.x)
	Median	xxx	x.x	xxx	xx	x.x	x.xx	x.x	xx
	Min, Max	xxx, xxx	x.x, x.x	xxx, xxx	xx, xx	x.x, x.x	x.xx, x.xx	x.x, x.x	xx, xx
Day 3	n	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xxx (xx.x)	x.x (x.x)	xxx (xx.x)	xx (xx.x)	x.x (x.x)	x.xx (x.xx)	x.x (x.x)	xx (xx.x)
	Median	xxx	x.x	xxx	xx	x.x	x.xx	x.x	xx
etc	Min, Max	xxx, xxx	x.x, x.x	xxx, xxx	xx, xx	x.x, x.x	x.xx, x.xx	x.x, x.x	xx, xx

K=Potassium, CL=Chloride, BICARB=Bicarbonate, CA=Calcium, MG=Magnesium, UREAN=Urea nitrogen, CREAT=Creatinine

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

[Programming Note: For out of range results, use bold font and superscript L or H]

Table 14.3.5.4: Summary of Clinical Laboratory Test Results, Liver Function
Safety Population

Time Point		ALT (ukat/L)	AST (ukat/L)	ALP (ukat/L)	TBILI (umol/L)	DBILI (umol/L)	IBILI (umol/L)	LDH (ukat/L)
Screening	n	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.xx (x.xx)
	Median	x.xx	x.xx	x.xx	x.x	x.x	x.x	x.xx
	Min, Max	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.x, x.x	x.x, x.x	x.x, x.x	x.xx, x.xx
Day -1	n	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.xx (x.xx)
	Median	x.xx	x.xx	x.xx	x.x	x.x	x.x	x.xx
	Min, Max	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.x, x.x	x.x, x.x	x.x, x.x	x.xx, x.xx
Day 2	n	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.xx (x.xx)
	Median	x.xx	x.xx	x.xx	x.x	x.x	x.x	x.xx
	Min, Max	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.x, x.x	x.x, x.x	x.x, x.x	x.xx, x.xx
	n	xx	xx	xx	xx	xx	xx	xx
Day 3	Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.xx (x.xx)
	Median	x.xx	x.xx	x.xx	x.x	x.x	x.x	x.xx
etc	Min, Max	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.x, x.x	x.x, x.x	x.x, x.x	x.xx, x.xx

ALT=Alanine transaminase, AST=Aspartate transaminase, ALP=Alkaline phosphatase, TBILI=Total bilirubin, DBILI=Direct bilirubin, IBILI=Indirect bilirubin, LDH=Lactate dehydrogenase.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Table 14.3.5.5: Summary of Clinical Laboratory Test Results, Other Serum Chemistry
Safety Population

Time Point		TPROT (g/L)	GLUC (mmol/L)	ALB (g/L)	URAC (umol/L)	CPK (ukat/L)	AMY (ukat/L)	LIP (ukat/L)
Screening	n	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx (xx.x)	xxx (xx.x)	xx (xx.x)	xxx (xx.x)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
	Median	xx	xxx	xx	xxx	x.xx	x.xx	x.xx
	Min, Max	xx, xx	xxx, xxx	xx, xx	xxx, xxx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx
Day -1	n	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx (xx.x)	xxx (xx.x)	xx (xx.x)	xxx (xx.x)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
	Median	xx	xxx	xx	xxx	x.xx	x.xx	x.xx
	Min, Max	xx, xx	xxx, xxx	xx, xx	xxx, xxx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx
Day 2	n	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx (xx.x)	xxx (xx.x)	xx (xx.x)	xxx (xx.x)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
	Median	xx	xxx	xx	xxx	x.xx	x.xx	x.xx
	Min, Max	xx, xx	xxx, xxx	xx, xx	xxx, xxx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx
	n	xx	xx	xx	xx	xx	xx	xx
Day 3	Mean (SD)	xx (xx.x)	xxx (xx.x)	xx (xx.x)	xxx (xx.x)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
	Median	xx	xxx	xx	xxx	x.xx	x.xx	x.xx
etc	Min, Max	xx, xx	xxx, xxx	xx, xx	xxx, xxx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx

TPROT=Total protein, GLUC=Glucose, ALB=Albumin, URAC=Uric acid, CPK=Creatinine phosphokinase, AMY=Amylase, LIP=Lipase

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Table 14.3.5.6: Summary of Clinical Laboratory Test Results, Urinalysis, Part 1
Safety Population

Time Point		pH	SpG (g/mL)	GLUC	KET	BILI	CREAT	SOD
Screening	n(%) Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%) Abnormal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day -1	n(%) Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%) Abnormal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 2	n(%) Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%) Abnormal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 3	n(%) Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%) Abnormal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 7	n(%) Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%) Abnormal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 20	n(%) Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%) Abnormal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc								

SpG=Specific gravity, GLUC=Glucose, KET=Ketones, BILI=Bilirubin, CREAT=Creatinine, SOD=Sodium.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

[Programming Note: For out of range results, use bold font and superscript A.]

Table 14.3.5.7: Summary of Clinical Laboratory Test Results, Urinalysis, Part 2
Safety Population

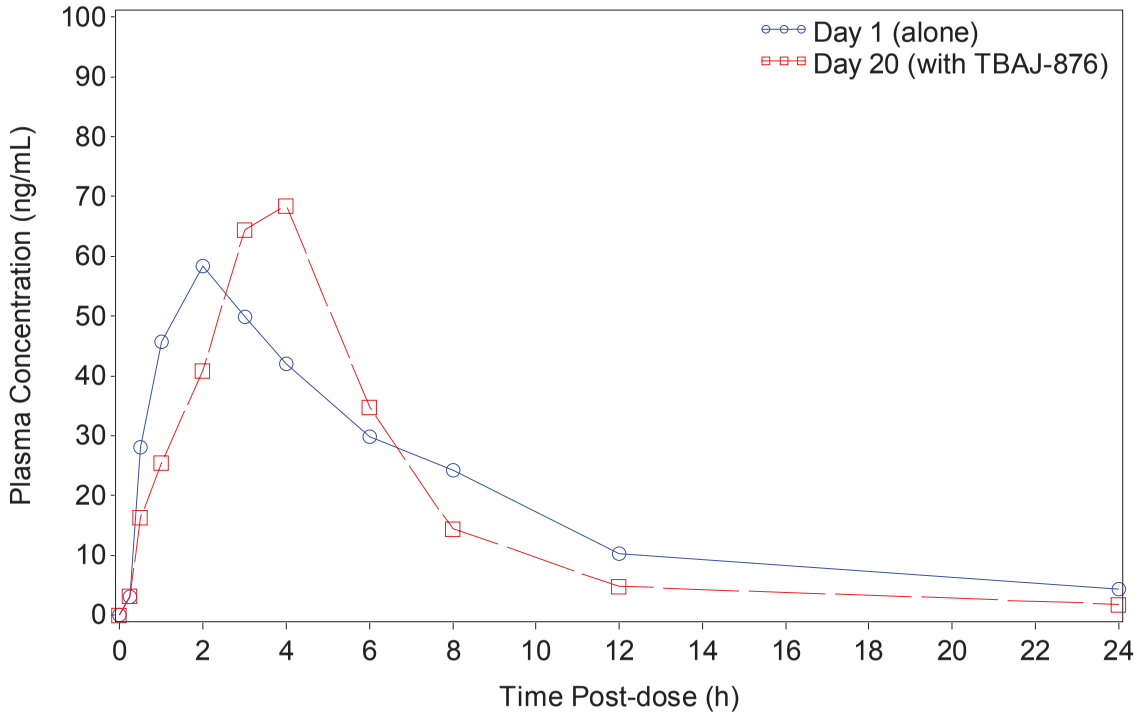
Time Point		PROT	OCC	NIT	LEUK	Microscopic Examination (if indicated)
Screening	n(%) Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%) Abnormal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day -1	n(%) Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%) Abnormal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 2	n(%) Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%) Abnormal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 3	n(%) Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%) Abnormal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 7	n(%) Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%) Abnormal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 20	n(%) Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%) Abnormal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc						

PROT=Protein, OCC=Occult blood, NIT=Nitrite, LEUK=Leukocyte esterase.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

TB Alliance
Protocol Number: TBAJ-876-CL002

Figure 14.2.1: Mean Plasma Midazolam Concentration vs Time Post-dose
PK Population



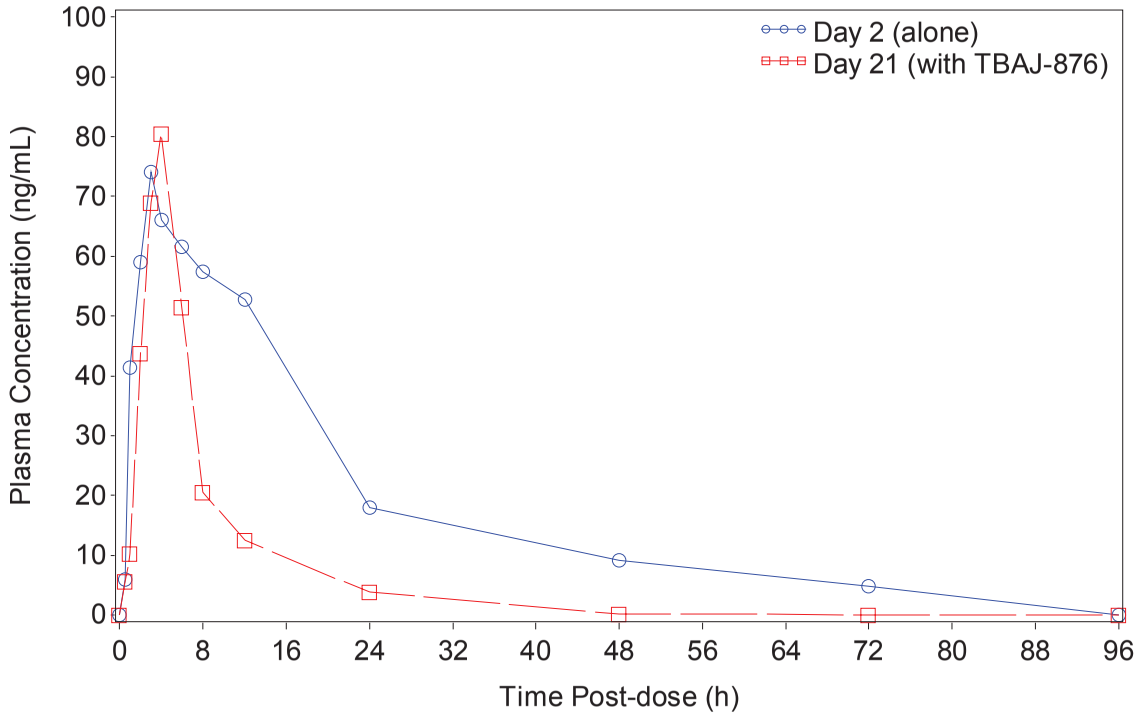
Note: Concentrations BLOQ are included as 0.

Generated on ... by ... / Uses: ADPC / Reference: Table 14.2.1.2.1.

Note: Use similar formats for all analytes and for individual subject plots.

TB Alliance
Protocol Number: TBAJ-876-CL002

Figure 14.2.3: Mean Plasma Digoxin Concentration vs Time Post-dose
PK Population

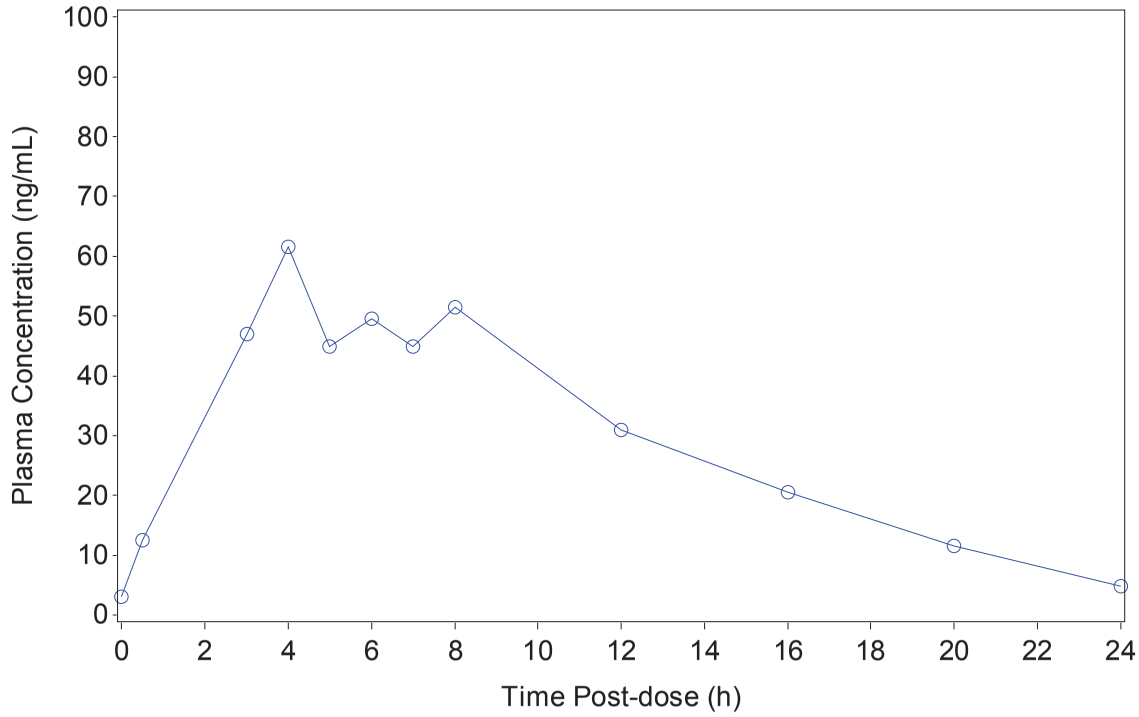


Note: Concentrations BLOQ are included as 0.

Generated on ... by ... / Uses: ADPC / Reference: Table 14.2.1.2.1.

TB Alliance
Protocol Number: TBAJ-876-CL002

Figure 14.2.4: Mean Day 17 Plasma TBAJ-876 Concentration vs Time Post-dose
PK Population



Note: Concentrations BLOQ are included as 0.

Generated on ... by ... / Uses: ADPC / Reference: Table 14.2.1.2.1.

TB Alliance
Protocol Number: TBAJ-876-CL002

Listing 16.1.7: Subject Enrollment

All Enrolled Subjects

Subject	Date of Informed Consent	Satisfy All I/E Criteria?	Date-Time of Enrollment	Enrollment Number	Group
xxx	xxxx-xx-xx	xxx	xxxx-xx-xxTxx:xx	xxx	1
xxx	xxxx-xx-xx	xxx	xxxx-xx-xxTxx:xx	xxx	1
xxx	xxxx-xx-xx	xxx	xxxx-xx-xxTxx:xx	xxx	1

Generated on XX/XX/XX XX:XX by XXXX/ Uses: XXXX

[Programming Note: List all enrolled subjects in order of their date-time of enrollment.]

TB Alliance
Protocol Number: TBAJ-876-CL002

Page X of Y

Listing 16.2.1.1: Screen Failures

Subject	Date of Informed Consent	Date of Screening	Sex	Race	Ethnicity	Reason for Screen Failure
xxx	xxxx-xx-xx	xxxx-xx-xx	xxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxx	xxxx-xx-xx	xxxx-xx-xx	xxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxx	xxxx-xx-xx	xxxx-xx-xx	xxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxx	xxxx-xx-xx	xxxx-xx-xx	xxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxx	xxxx-xx-xx	xxxx-xx-xx	xxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxx	xxxx-xx-xx	xxxx-xx-xx	xxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxx	xxxx-xx-xx	xxxx-xx-xx	xxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx

Generated on XX/XX/XX:XXXXXXXX by XXXX/ Uses: XXXX

[Programming Note: In Reason for Screen Failure, include list of inclusion criteria not met along with Primary Reason for Screen Failure and Comments (IECOMM).]

TB Alliance
Protocol Number: TBAJ-876-CL002

Page X of Y

Listing 16.2.1.2: Subject Disposition
All Enrolled Subjects

Subject	Screening Date	Date Enrolled	Date of Last Visit	Date of Last Contact	Completion Status
xxx	xxxx-xx-xx (-xx)	xxxx-xx-xx (1)	xxxx-xx-xx (xx)	xxxx-xx-xx (xx)	xxxxxxxxxxxxxxxxxxxxx
xxx	xxxx-xx-xx (-xx)	xxxx-xx-xx (1)	xxxx-xx-xx (xx)	xxxx-xx-xx (xx)	xxxxxxxxxxxxxxxxxxxxx
xxx	xxxx-xx-xx (-xx)	xxxx-xx-xx (1)	xxxx-xx-xx (xx)	xxxx-xx-xx (xx)	xxxxxxxxxxxxxxxxxxxxx
xxx	xxxx-xx-xx (-xx)	xxxx-xx-xx (1)	xxxx-xx-xx (xx)	xxxx-xx-xx (xx)	xxxxxxxxxxxxxxxxxxxxx
xxx	xxxx-xx-xx (-xx)	xxxx-xx-xx (1)	xxxx-xx-xx (xx)	xxxx-xx-xx (xx)	xxxxxxxxxxxxxxxxxxxxx
xxx	xxxx-xx-xx (-xx)	xxxx-xx-xx (1)	xxxx-xx-xx (xx)	xxxx-xx-xx (xx)	xxxxxxxxxxxxxxxxxxxxx

Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

[Programming Note: Study completion status will include reason for discontinuation (DSDECOD and DSCMTS)]

Listing 16.2.2: Protocol Deviations
All Enrolled Subjects

Subject	Category	Date (Day)	Protocol Deviation	Protocol Deviation Type	Action Taken
xxx	Major	xxxx-xx-xx (x)	xxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	Major	xxxx-xx-xx (x)	xxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxx	Major	xxxx-xx-xx (xx)	xxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Listing 16.2.4.1: Demographics and Baseline Characteristics
All Enrolled Subjects

Subject	Age	Gender	Race	Ethnicity	Weight (kg)		Height (cm)	BMI (kg/m^2)
					Screening	Day -1		
xxx	xx	Male	xxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxx	xx.x	xx.x	xxx.x	xx.x
xxx	xx	Female	xxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxx	xx.x	xx.x	xxx.x	xx.x
xxx	xx	Male	xxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxx	xx.x	xx.x	xxx.x	xx.x
xxx	xx	Female	xxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxx	xx.x	xx.x	xxx.x	xx.x
xxx	xx	Female	xxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxx	xx.x	xx.x	xxx.x	xx.x
xxx	xx	Male	xxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxx	xx.x	xx.x	xxx.x	xx.x

Note: BMI = Body Mass Index

Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

Listing 16.2.4.2: Prior and Concomitant Medication
Safety Population

Subject	Prior or Concomitant?	WHO Preferred Term (Verbatim Term) / ATC Classification	Indication / Dose Unit / Frequency / Route	Start Date (Day)-Stop Date (Day)
xxx	Concomitant	xxxxxxxxxxxxxx (xxxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxx / xxxxx xxxx / xxxxxxxxxxxx / xxxxxxxxxxxxxx	xxxx-xx-xx (xx) - xxxx-xx-xx (xx)

Note: Study day is shown only if it is on or after Day 1, or within 30 days prior to Day 1.

Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

[Programming Note: List medications in ascending order of start date for each subject.]

Listing 16.2.4.3: Medical History
Safety Population

Subject	Diagnosis	Start Date (Day)	End Date (Day)	Medication Taken Currently?
xxx	xxxxxxxxxxxxxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxx-xx-xx (xx)	xxx
	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxx-xx-xx (xx)	Ongoing	xxx
xxx	xxxxxxxxxxxxxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxx-xx-xx (xx)	xxx

Note: Study day is shown only if it is within 30 days prior to Day 1.

Generated on XX/XX/XX:XXXX by XXXXX/ Uses: XXXX

Listing 16.2.5.1: Plasma Midazolam Concentrations
PK Population

Subject	Day	Date-time of Dosing		Pre-dose	15 mins	30 mins	1 hr	2 hrs	3 hrs	4 hrs	6 hrs	8 hrs	12 hrs	24 hrs
xxx	1	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	20	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
xxx	1	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	20	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Listing 16.2.5.2: Plasma 1-Hydroxymidazolam Concentrations
PK Population

Subject	Day	Date-time of Dosing		Pre-dose	15 mins	30 mins	1 hr	2 hrs	3 hrs	4 hrs	6 hrs	8 hrs	12 hrs	24 hrs
xxx	1	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	20	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
xxx	1	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	20	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Listing 16.2.5.3: Plasma Digoxin Concentrations
PK Population

Subj	Day	Date-time of Dosing		Pre-dose	30 mins	1 hr	2 hrs	3 hrs	4 hrs	6 hrs	8 hrs	12 hrs	24 hrs	48 hrs	72 hrs	96 hrs
xxx	2	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	21	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
xxx	2	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	21	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

TB Alliance
Protocol Number: TBAJ-876-CL002

Page X of Y

Listing 16.2.5.4: Plasma TBAJ-876 Concentrations
PK Population

Subject	**Day**	**Date-time of Dosing**		**Pre-dose**	**30 mins**	**3 hrs**	**4 hrs**	**5 hrs**	**6 hrs**	**7 hrs**	**8 hrs**	**12 hrs**	**16 hrs**	**20 hrs**	**24 hrs**
xxx	17	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
xxx	17	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
xxx	17	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
xxx	17	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

TB Alliance
Protocol Number: TBAJ-876-CL002

Page X of Y

Listing 16.2.5.5: Plasma M2 Concentrations
PK Population

Subject	Day	Date-time of Dosing		Pre-dose	30 mins	3 hrs	4 hrs	5 hrs	6 hrs	7 hrs	8 hrs	12 hrs	16 hrs	20 hrs	24 hrs
xxx	17	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
xxx	17	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
xxx	17	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
xxx	17	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

TB Alliance
Protocol Number: TBAJ-876-CL002

Page X of Y

Listing 16.2.5.6: Plasma M3 Concentrations
PK Population

Subject	Day	Date-time of Dosing		Pre-dose	30 mins	3 hrs	4 hrs	5 hrs	6 hrs	7 hrs	8 hrs	12 hrs	16 hrs	20 hrs	24 hrs
xxx	17	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
xxx	17	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
xxx	17	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
xxx	17	xxxx-xx-xxTxx:xx	*Sample Time*	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx	xx:xx
			Concentration (ng/mL)	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

TB Alliance
Protocol Number: TBAJ-876-CL002

Page X of Y

Listing 16.2.6.1: Midazolam Pharmacokinetic Parameters
PK Population

Subj	**Day**	**Date-time of Dosing**	**AUC_{0-last} (ng.hr/mL)**	**AUC_{0-inf} (ng.hr/mL)**	**C_{max} (ng/mL)**	**t_{max} (hr)**	**k_{el} (/hr)**	**$t_{1/2}$ (hr)**	**CL/F (L/hr)**	**V_Z/F (L)**
xxx	1	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x
	20	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x
xxx	1	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x
	20	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x
xxx	1	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x
	20	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

TB Alliance
Protocol Number: TBAJ-876-CL002

Page X of Y

Listing 16.2.6.2: 1-Hydroxymidazolam Pharmacokinetic Parameters
PK Population

Subj	Day	Date-time of Dosing	$AUC_{0\text{-last}}$ (ng.hr/mL)	$AUC_{0\text{-inf}}$ (ng.hr/mL)	C_{max} (ng/mL)	t_{max} (hr)	k_{el} (/hr)	$t_{1/2}$ (hr)	CL/F (L/hr)	V_Z/F (L)
xxx	1	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x
	20	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x
xxx	1	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x
	20	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x
xxx	1	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x
	20	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

TB Alliance
Protocol Number: TBAJ-876-CL002

Page X of Y

Listing 16.2.6.3: Digoxin Pharmacokinetic Parameters
PK Population

Subj	Day	Date-time of Dosing	AUC_{0-last} (ng.hr/mL)	AUC_{0-inf} (ng.hr/mL)	C_{max} (ng/mL)	t_{max} (hr)	k_{el} (/hr)	$t_{1/2}$ (hr)	CL/F (L/hr)	V_Z/F (L)
xxx	2	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x
	21	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x
xxx	2	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x
	21	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x
xxx	2	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x
	21	xxxx-xx-xxTxx:xx	xxxx	xxxx	xx.x	x.xx	x.xxxx	xx.x	xx.x	xx.x

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

TB Alliance
Protocol Number: TBAJ-876-CL002

Page X of Y

Listing 16.2.6.4: TBAJ-876 Dosing
All Enrolled Subjects

	Time of Dosing (Day)																		
Subj	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**
XXX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX
XXX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX
XXX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX
XXX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX
XXX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX
XXX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX
XXX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX	XX:XX

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

TB Alliance
Protocol Number: TBAJ-876-CL002

Page X of Y

Listing 16.2.6.5: TBAJ-876 Day 17 Pharmacokinetic Parameters
PK Population

	TBAJ-876				M2				M3			
Subj	**AUC_{0-24} (ng.hr/mL)**	**C_{max} (ng/mL)**	**t_{max} (hr)**	**C_{trough} (ng/mL)**	**AUC_{0-24} (ng.hr/mL)**	**C_{max} (ng/mL)**	**t_{max} (hr)**	**C_{trough} (ng/mL)**	**AUC_{0-24} (ng.hr/mL)**	**C_{max} (ng/mL)**	**t_{max} (hr)**	**C_{trough} (ng/mL)**
XXX	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X
XXX	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X
XXX	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X
XXX	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X
XXX	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X
XXX	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X
XXX	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X
XXX	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X	XXXX	XX.X	X.XX	XX.X

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Listing 16.2.7.1: Adverse Events
Safety Population

Subject	MedDRA Preferred Term (Verbatim Term) / MedDRA SOC Term	Start Date-Time (Day) - Stop Date-Time (Day) / Date-Time (Day) Reported	TEAE? / Severity / Outcome / Relationship to Study Drug (Regimen*)	Action Taken with Study Product / Other Action Taken / Serious? (Criteria Met)
xxx	xxxxxxxxxxxxxxxxxxxxxxxxx (xxxxxxxxxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxxxxxxx	xxxx-xx-xxTxx:xx (xx) – xxxx-xx-xxTxx:xx (xx) / xxxx-xx-xxTxx:xx (xx)	xxx / xxxxxxxx / xxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxx (xxxxxx)	xxxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxxxxxxxxx / xx
	xxxxxxxxxxxxxxxxxxxxxxxxx (xxxxxxxxxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxxxxxxx	xxxx-xx-xxTxx:xx (xx) – Ongoing / xxxx-xx-xxTxx:xx (xx)	xxx / xxxxxxxx / xxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxx (xxxxxx)	xxxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxxxxxxxxx / xx
xxx	xxxxxxxxxxxxxxxxxxxxxxxxx (xxxxxxxxxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxxxxxxx	xxxx-xx-xxTxx:xx (xx) – xxxx-xx-xxTxx:xx (xx) / xxxx-xx-xxTxx:xx (xx)	xxx / xxxxxxxx / xxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxx (xxxxxx)	xxxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxxxxxxxxx / xx

TEAE= Treatment-emergent adverse event (onset on or after Day 1); SOC=System organ class

Generated on XX/XX/XX:XXXX by XXXX / Uses: XXXX

**Note: For Relationship to Study Drug Regimen, show "Not related" if data show "Not related" for all study products. Otherwise, list degree of relationship and attributed regimen (TBAJ-876, midazolam, digoxin, TBAJ-876 plus midazolam, etc).*

Listing 16.2.7.2: Serious Adverse Events and Adverse Events Leading to Study Discontinuation
Safety Population

Subject	MedDRA Preferred Term (Verbatim Term) / MedDRA SOC Term	Start Date-Time (Day) - Stop Date-Time (Day) / Date-Time (Day) Reported	TEAE? / Severity / Outcome / Relationship to Study Drug Regimen	Action Taken with Study Product / Other Action Taken / Serious? (Criteria Met)
xxx	xxxxxxxxxxxxxxxxxxxxxxxxx (xxxxxxxxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxxxxxxx	xxxx-xx-xxTxx:xx (xx) – xxxx-xx-xxTxx:xx (xx) / xxxx-xx-xxTxx:xx (xx)	xxx / xxxxxxxx / xxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxxxxxxxx / xx
	xxxxxxxxxxxxxxxxxxxxxxxxx (xxxxxxxxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxxxxxxx	xxxx-xx-xxTxx:xx (xx) – Ongoing / xxxx-xx-xxTxx:xx (xx)	xxx / xxxxxxxx / xxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxxxxxxxx / xx
xxx	xxxxxxxxxxxxxxxxxxxxxxxxx (xxxxxxxxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxxxxxxx	xxxx-xx-xxTxx:xx (xx) – xxxx-xx-xxTxx:xx (xx) / xxxx-xx-xxTxx:xx (xx)	xxx / xxxxxxxx / xxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxxxxxxxx / xx

TEAE= Treatment-emergent adverse event (onset on or after Day 1); SOC=System organ class

Generated on XX/XX/XX:XXXX by XXXX / Uses: XXXX

Note: For Relationship to Study Drug Regimen, show "Not related" if data show "Not related" for all study products. Otherwise, list degree of relationship and attributed regimen (TBAJ-876, midazolam, digoxin, TBAJ-876 plus midazolam, etc).

Listing 16.2.7.3: Cardiovascular Adverse Events
Safety Population

Subject	MedDRA Preferred Term (Verbatim Term) / MedDRA SOC Term	Start Date-Time (Day) - Stop Date-Time (Day) / Date-Time (Day) Reported	TEAE? / Severity / Outcome / Relationship to Study Drug Regimen	Action Taken with Study Product / Other Action Taken / Serious? (Criteria Met)	Vital Signs Taken Closest to Cardiovascular Event: Systolic BP (mmHg)/Diastolic BP (mmHg) (Heart Rate (bpm))
xxx	xxxxxxxxxxxxxxxxxxxxxxxxx (xxxxxxxxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxxxxxxx	xxxx-xx-xxTxx:xx (xx) – xxxx-xx-xxTxx:xx (xx) / xxxx-xx-xxTxx:xx (xx)	xxx / xxxxxxxx / xxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxxxxxxxxx / xx	xxx/xx (xx)
	xxxxxxxxxxxxxxxxxxxxxxxxx (xxxxxxxxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxxxxxxx	xxxx-xx-xxTxx:xx (xx) – Ongoing / xxxx-xx-xxTxx:xx (xx)	xxx / xxxxxxxx / xxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxxxxxxxxx / xx	xxx/xx (xx)
xxx	xxxxxxxxxxxxxxxxxxxxxxxxx (xxxxxxxxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxxxxxxx	xxxx-xx-xxTxx:xx (xx) – xxxx-xx-xxTxx:xx (xx) / xxxx-xx-xxTxx:xx (xx)	xxx / xxxxxxxx / xxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxx / xxxxxxxxxxxxxxxxxxxxxx / xx	xxx/xx (xx)

TEAE= Treatment-emergent adverse event (onset on or after Day 1); SOC=System organ class

Generated on XX/XX/XX:XXXX by XXXX / Uses: XXXX

Note: For Relationship to Study Drug Regimen, show "Not related" if data show "Not related" for all study products. Otherwise, list degree of relationship and attributed regimen (TBAJ-876, midazolam, digoxin, TBAJ-876 plus midazolam, etc).

Listing 16.2.8.1: Physical Examinations
Safety Population

Subject	Time Point	Date-Time (Day)	Body System	Findings	Presence of Heart Murmur
xxx	Screening	xxxx-xx-xxTxx:xx (-x)	All systems	Normal	xxx
	Day -1	xxxx-xx-xxTxx:xx (-x)	All systems	Normal	xxx
	Day 2	xxxx-xx-xxTxx:xx (x)	All systems	Normal	xxx
	Day 3	xxxx-xx-xxTxx:xx (x)	xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx
			xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx
	Day 4	xxxx-xx-xxTxx:xx (x)	All systems	Normal	xxx
	Day 5	xxxx-xx-xxTxx:xx (x)	All systems	Normal	xxx
	Day 25/ET	xxxx-xx-xxTxx:xx (x)	All systems	Normal	xxx
xxx	Screening	xxxx-xx-xxTxx:xx (-x)	All systems	Normal	xxx
	etc				

Note: Full physical examination includes HEENT, neck, heart, respiratory, abdomen, musculoskeletal, neurological status, skin, and other. Body systems were normal if not otherwise shown.

Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

Listing 16.2.8.2: Vital Signs Measurements
Safety Population

Subj	Time Point	Date-Time (Day)	Supine Systolic BP (mmHg)	Supine Diastolic BP (mmHg)	Supine Heart Rate (bpm)	Temp (C)	Resp Rate (bpm)	Pulse Oximetry (%)	Supine Systolic BP (mmHg)	Supine Diastolic BP (mmHg)	Supine Heart Rate (bpm)
xxx	Screening	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day -1	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 1	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Pre-dose	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	0.5 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	1 hr	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	2 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	6 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	12 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 2	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Pre-dose	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	0.5 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	1 hr	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	2 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	6 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	12 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 6	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Pre-dose	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	0.5 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	1 hr	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	2 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx

Note: On Days 7 through 19, vital signs are taken 6 hours after dosing. Supine measurements are taken after at least 2 minutes in supine position, and standing measurements are taken after at least 1 minute standing.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Listing 16.2.8.2: Vital Signs Measurements
Safety Population

Subj	Time Point	Date-Time (Day)	Supine Systolic BP (mmHg)	Supine Diastolic BP (mmHg)	Supine Heart Rate (bpm)	Temp (C)	Resp Rate (bpm)	Pulse Oximetry (%)	Supine Systolic BP (mmHg)	Supine Diastolic BP (mmHg)	Supine Heart Rate (bpm)
xxx	Day 6	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	6 hrs	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	12 hrs	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 7	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 8	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 9	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 10	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 11	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 12	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 13	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 14	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 15	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 16	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 17	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 18	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 19	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 20	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Pre-dose	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	0.5 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	1 hr	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	2 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx

Note: On Days 7 through 19, vital signs are taken 6 hours after dosing. Supine measurements are taken after at least 2 minutes in supine position, and standing measurements are taken after at least 1 minute standing.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Listing 16.2.8.2: Vital Signs Measurements
Safety Population

Subj	Time Point	Date-Time (Day)	Supine Systolic BP (mmHg)	Supine Diastolic BP (mmHg)	Supine Heart Rate (bpm)	Temp (C)	Resp Rate (bpm)	Pulse Oximetry (%)	Supine Systolic BP (mmHg)	Supine Diastolic BP (mmHg)	Supine Heart Rate (bpm)
xxx	Day 20	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	6 hrs	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	12 hrs	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 21	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Pre-dose	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	0.5 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	1 hr	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	2 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	6 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	12 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 24	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Pre-dose	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	0.5 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	1 hr	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	2 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	6 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	12 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx
	Day 25/ET	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xx.x	xx	xx.x	xxx	xxx	xxx

Note: On Days 7 through 19, vital signs are taken 6 hours after dosing. Supine measurements are taken after at least 2 minutes in supine position, and standing measurements are taken after at least 1 minute standing.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Listing 16.2.8.3: Electrocardiogram (ECG) Results
Safety Population

Subject	Time Point	Date-Time (Day)	HR (bpm)	PR (msec)	QRS (msec)	QT (msec)	QTcF (msec)	Investigator's Assessment / Comments
xxx	Screening	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxx
	Day -1	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxx
	Day 2	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxx
	Pre-dose	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxx
	0.5 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxx
	1 hr	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxx
	2 hrs	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxx
	6 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxx
	12 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxx
	Day 3	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxx
	Day 7	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxx
	Day 20	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxx
	Day 21	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxx
	Pre-dose	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxx
	0.5 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxx
	1 hr	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxx
	2 hrs	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxx
	6 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxx
	12 hrs	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxx
	Day 22	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxx
	Day 25/ET	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xxx	xxx	xxxxxxxxxxxxxxxx

HR=Heart rate, PR=PR interval, QRS=QRS duration, QT=QT interval, QTcF=Corrected QT interval; ET=Early termination.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Note: Blank line after every subject. Repeat subject number at the top of each page.

TB Alliance Page X of Y
Protocol Number: TBAJ-876-CL002

Listing 16.2.8.4.1: Clinical Laboratory Test Results, Hematology and Coagulation
Safety Population

Subject	Time Point	Date-Time (Day)	HCT (ratio)	HGB (g/L)	RBC (10^12/L)	WBC (10^9/L)	PLAT (10^9/L)	RETI (ratio)	aPTT2 (sec)	PT2 (sec)
xxx	Screening	xxxx-xx-xxTxx:xx (-x)	.xxx	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Day -1	xxxx-xx-xxTxx:xx (-x)	.xxx	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Day 2	xxxx-xx-xxTxx:xx (x)	.xxx	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Day 3	xxxx-xx-xxTxx:xx (x)	**.xxx** ^{L}	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Day 7	xxxx-xx-xxTxx:xx (x)	.xxx	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Day 20	xxxx-xx-xxTxx:xx (xx)	.xxx	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Day 21	xxxx-xx-xxTxx:xx (xx)	**.xxx** ^{L}	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Day 22	xxxx-xx-xxTxx:xx (xx)	**.xxx** ^{L}	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Day 25/ET	xxxx-xx-xxTxx:xx (xx)	.xxx	xxx	x.xx	x.x	xxx	.xxx	xx	xx
xxx	Screening	xxxx-xx-xxTxx:xx (-x)	.xxx	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Day -1	xxxx-xx-xxTxx:xx (-x)	.xxx	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Day 2	xxxx-xx-xxTxx:xx (x)	.xxx	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Day 3	xxxx-xx-xxTxx:xx (x)	**.xxx** ^{L}	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Day 7	xxxx-xx-xxTxx:xx (x)	.xxx	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Day 20	xxxx-xx-xxTxx:xx (xx)	.xxx	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Day 21	xxxx-xx-xxTxx:xx (xx)	**.xxx** ^{L}	xxx	x.xx	x.x	xxx	.xxx	xx	xx
	Day 22	xxxx-xx-xxTxx:xx (xx)	**.xxx** ^{L}	xxx	x.xx	x.x	xxx	.xxx	xx	xx

H=High, L=Low, ET=Early Termination.
HCT = Hematocrit; HGB = Hemoglobin; RBC = Erythrocytes; WBC=Leukocytes; PLAT = Platelets, RETI=Reticulocytes, aPTT2=Activated partial thromboplastin time, PT2=Prothrombin time.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

[Programming Note: For out of range results, use bold font and superscript L or H as shown in the example]

Listing 16.2.8.4.2: Clinical Laboratory Test Results, Differential Blood Count
Safety Population

			NEUT		LYM		MONO		EOS		BASO	
Subject	**Time Point**	**Date-Time (Day)**	**(10^9/L)**	**(Ratio)**	**(10^9/L)**	**(Ratio)**	**(10^9/L)**	**(Ratio)**	**(10^9/L)**	**(Ratio)**	**(10^9/L)**	**(Ratio)**
xxx	Screening	xxxx-xx-xxTxx:xx (-xx)	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx
	Day -1	xxxx-xx-xxTxx:xx (-x)	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx
	Day 2	xxxx-xx-xxTxx:xx (x)	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx
	Day 3	xxxx-xx-xxTxx:xx (x)	x.x	x.xx	x.x	x.xx	**x.x** ^{L}	**x.xx** ^{L}	x.x	x.xx	x.x	x.xx
	Day 7	xxxx-xx-xxTxx:xx (x)	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx
	Day 20	xxxx-xx-xxTxx:xx (xx)	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx
	Day 21	xxxx-xx-xxTxx:xx (xx)	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx
	Day 22	xxxx-xx-xxTxx:xx (xx)	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx
	Day 25/ET	xxxx-xx-xxTxx:xx (xx)	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx	x.x	x.xx

H = High; L = Low; ET=Early Termination.
NEUT = Neutrophils; LYM = Lymphocytes; MONO = Monocytes; EOS = Eosinophils; BASO = Basophils

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

[Programming Note: For out of range results, use bold font and superscript L or H as shown in the example]

Listing 16.2.8.4.3: Clinical Laboratory Test Results, Electrolytes and Renal Function
Safety Population

Subject	Time Point	Date-Time (Day)	SODIUM (mmol/L)	K (mmol/L)	CL (mmol/L)	BICARB (mmol/L)	CA (mmol/L)	MG (mmol/L)	UREAN (mmol/L)	CREAT (umol/L)
xxx	Screening	xxxx-xx-xxTxx:xx (-xx)	xxx.x	x.x	xxx	xx	x.x	x.xx	x.x	xx
	Day -1	xxxx-xx-xxTxx:xx (-x)	xxx.x	x.x	xxx	xx	x.x	x.xx	x.x	xx
	Day 2	xxxx-xx-xxTxx:xx (x)	xxx.x	x.x	xxx	xx	x.x	x.xx	x.x	xx
	Day 3	xxxx-xx-xxTxx:xx (x)	xxx.x	x.x	xxx	xx	x.x	x.xx	x.x	xx
	Day 7	xxxx-xx-xxTxx:xx (x)	xxx.x	x.x	xxx	xx	x.x	x.xx	x.x	xx
	Day 20	xxxx-xx-xxTxx:xx (xx)	xxx.x	x.x	xxx	xx	x.x	x.xx	x.x	xx
	Day 21	xxxx-xx-xxTxx:xx (xx)	xxx.x	x.x	xxx	xx	x.x	x.xx	x.x	xx
	Day 22	xxxx-xx-xxTxx:xx (xx)	xxx.x	x.x	xxx	xx	x.x	x.xx	x.x	xx
	Day 25/ET	xxxx-xx-xxTxx:xx (xx)	xxx.x	x.x	xxx	xx	x.x	x.xx	x.x	xx

H=High, L=Low, ET=Early Termination.
K=Potassium, CL=Chloride, BICARB=Bicarbonate, CA=Calcium, MG=Magnesium, UREAN=Urea nitrogen, CREAT=Creatinine

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

[Programming Note: For out of range results, use bold font and superscript L or H]

TB Alliance Page X of Y
Protocol Number: TBAJ-876-CL002

Listing 16.2.8.4.4: Clinical Laboratory Test Results, Liver Function
Safety Population

Subject	Time Point	Date-Time (Day)	ALT (ukat/L)	AST (ukat/L)	ALP (ukat/L)	TBILI (umol/L)	DBILI (umol/L)	IBILI (umol/L)	LDH (ukat/L)
xxx	Screening	xxxx-xx-xxTxx:xx (-xx)	x.xx	x.xx	x.xx	x.x	x.x	x.x	x.xx
	Day -1	xxxx-xx-xxTxx:xx (-x)	x.xx	x.xx	x.xx	x.x	x.x	x.x	x.xx
	Day 2	xxxx-xx-xxTxx:xx (x)	x.xx	x.xx	x.xx	x.x	x.x	x.x	x.xx
	Day 3	xxxx-xx-xxTxx:xx (x)	x.xx	x.xx	x.xx	x.x	x.x	x.x	x.xx
	Day 7	xxxx-xx-xxTxx:xx (x)	x.xx	x.xx	x.xx	x.x	x.x	x.x	x.xx
	Day 20	xxxx-xx-xxTxx:xx (xx)	x.xx	x.xx	x.xx	x.x	x.x	x.x	x.xx
	Day 21	xxxx-xx-xxTxx:xx (xx)	x.xx	x.xx	x.xx	x.x	x.x	x.x	x.xx
	Day 22	xxxx-xx-xxTxx:xx (xx)	x.xx	x.xx	x.xx	x.x	x.x	x.x	x.xx
	Day 25/ET	xxxx-xx-xxTxx:xx (xx)	x.xx	x.xx	x.xx	x.x	x.x	x.x	x.xx

H=High, L=Low, ET=Early Termination.
ALT=Alanine transaminase, AST=Aspartate transaminase, ALP=Alkaline phosphatase, TBILI=Total bilirubin, DBILI=Direct bilirubin, IBILI=Indirect bilirubin, LDH=Lactate dehydrogenase.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

[Programming Note: For out of range results, use bold font and superscript L or H]

TB Alliance Page X of Y
Protocol Number: TBAJ-876-CL002

Listing 16.2.8.4.5: Clinical Laboratory Test Results, Other Serum Chemistry
Safety Population

Subject	Time Point	Date-Time (Day)	TPROT (g/L)	GLUC (mmol/L)	ALB (g/L)	URAC (umol/L)	CPK (ukat/L)	AMY (ukat/L)	LIP (ukat/L)
xxx	Screening	xxxx-xx-xxTxx:xx (-xx)	xx	xxx	xx	xxx	x.xx	x.xx	x.xx
	Day -1	xxxx-xx-xxTxx:xx (-x)	xx	xxx	xx	xxx	x.xx	x.xx	x.xx
	Day 2	xxxx-xx-xxTxx:xx (x)	xx	xxx	xx	xxx	x.xx	x.xx	x.xx
	Day 3	xxxx-xx-xxTxx:xx (x)	xx	xxx	xx	xxx	x.xx	x.xx	x.xx
	Day 7	xxxx-xx-xxTxx:xx (x)	xx	xxx	xx	xxx	x.xx	x.xx	x.xx
	Day 20	xxxx-xx-xxTxx:xx (xx)	xx	xxx	xx	xxx	x.xx	x.xx	x.xx
	Day 21	xxxx-xx-xxTxx:xx (xx)	xx	xxx	xx	xxx	x.xx	x.xx	x.xx
	Day 22	xxxx-xx-xxTxx:xx (xx)	xx	xxx	xx	xxx	x.xx	x.xx	x.xx
	Day 25/ET	xxxx-xx-xxTxx:xx (xx)	xx	xxx	xx	xxx	x.xx	x.xx	x.xx

H=High, L=Low, ET=Early Termination.
TPROT=Total protein, GLUC=Glucose, ALB=Albumin, URAC=Uric acid, CPK=Creatinine phosphokinase, AMY=Amylase, LIP=Lipase

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

[Programming Note: For out of range results, use bold font and superscript L or H]

TB Alliance
Protocol Number: TBAJ-876-CL002

Listing 16.2.8.4.6: Clinical Laboratory Test Results, Urinalysis, Part 1
Safety Population

Subject	Time Point	Date-Time (Day)	pH	SpG (g/mL)	GLUC	KET	BILI	CREAT	SOD
xxx	Screening	xxxx-xx-xxTxx:xx (-xx)	x.x	x.xxx	xxx	xxx	xxx	xxx	xxx
	Day -1	xxxx-xx-xxTxx:xx (-x)	x.x	x.xxx	xxx	xxx	xxx	xxx	xxx
	Day 2	xxxx-xx-xxTxx:xx (x)	x.x	x.xxx	xxx	xxx	xxx	xxx	xxx
	Day 3	xxxx-xx-xxTxx:xx (x)	x.x	x.xxx	xxx	xxx	xxx	xxx	xxx
	Day 7	xxxx-xx-xxTxx:xx (x)	x.x	x.xxx	xxx	xxx	xxx	xxx	xxx
	Day 20	xxxx-xx-xxTxx:xx (xx)	x.x	x.xxx	xxx	xxx	xxx	xxx	xxx
	Day 21	xxxx-xx-xxTxx:xx (xx)	x.x	x.xxx	xxx	xxx	xxx	xxx	xxx
	Day 22	xxxx-xx-xxTxx:xx (xx)	x.x	x.xxx	xxx	xxx	xxx	xxx	xxx
	Day 25/ET	xxxx-xx-xxTxx:xx (xx)	x.x	x.xxx	xxx	xxx	xxx	xxx	xxx

A=Abnormal, ET=Early Termination.
SpG=Specific gravity, GLUC=Glucose, KET=Ketones, BILI=Bilirubin, CREAT=Creatinine, SOD=Sodium.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

[Programming Note: For out of range results, use bold font and superscript A.]

Listing 16.2.8.4.7: Clinical Laboratory Test Results, Urinalysis, Part 2
Safety Population

Subject	Time Point	Date-Time (Day)	PROT	OCC	NIT	LEUK	Microscopic Examination (if indicated)
xxx	Screening	xxxx-xx-xxTxx:xx (-xx)	xxx	xxx	xxx	xxx	
	Day -1	xxxx-xx-xxTxx:xx (-x)	xxx	xxx	xxx	xxx	
	Day 2	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	
	Day 3	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	
	Day 7	xxxx-xx-xxTxx:xx (x)	xxx	xxx	xxx	xxx	
	Day 20	xxxx-xx-xxTxx:xx (xx)	xxx	xxx	xxx	xxx	
	Day 21	xxxx-xx-xxTxx:xx (xx)	xxx	xxx	xxx	xxx	
	Day 22	xxxx-xx-xxTxx:xx (xx)	xxx	xxx	xxx	xxx	
	Day 25/ET	xxxx-xx-xxTxx:xx (xx)	xxx	xxx	xxx	xxx	

A=Abnormal, ET=Early Termination.
PROT=Protein, OCC=Occult blood, NIT=Nitrite, LEUK=Leukocyte esterase.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Listing 16.2.8.4.8: Laboratory Values Outside of Normal Range
Safety Population

Subject	Time Point	Date-Time (Day)	Panel	Parameter (Unit)	Reference Range	Result	Abnormality
xxx	Day -1	xxxx-xx-xxTxx:xx (x)	Chemistry	xxxxxx (xx)	xxxx, xxxx	xx.xx	Low
	Day 7	xxxx-xx-xxTxx:xx (x)	Chemistry	xxxxxx (xx)	xxxx, xxxx	xx.xx	Low
xxx	Day 22	xxxx-xx-xxTxx:xx (-x)	Hematology	xxxxxx (xx)	xxxx, xxxx	xx.xx	High

Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

[Programming Note: Use SDTM terms for parameter and unit.]

TB Alliance Page X of Y
Protocol Number: TBAJ-876-CL002

Listing 16.2.8.5: Childbearing Potential and Serum Pregnancy Test Results
Safety Population

		Screening		Check-in (Day -1)		Day 25 / Early Termination	
Subject	**Childbearing Potential**	**Date-Time**	**Result**	**Date-Time**	**Result**	**Date-Time**	**Result**
xxx	xxxxxxxxxxxxxxxxxxxxxxx	xxxx-xx-xxTxx:xx (-x)	xxxxxxxxxx	xxxx-xx-xxTxx:xx (-x)	xxxxxxxxxxx	xxxx-xx-xxTxx:xx (-x)	xxxxxxxxxxx
xxx	xxxxxxxxxxxxxxxxxxxxxxx	xxxx-xx-xxTxx:xx (-x)	xxxxxxxxxx	xxxx-xx-xxTxx:xx (-x)	xxxxxxxxxxx	xxxx-xx-xxTxx:xx (-x)	xxxxxxxxxxx
xxx	xxxxxxxxxxxxxxxxxxxx (FSH= xxx)	xxxx-xx-xxTxx:xx (-x)	xxxxxxxxxx	xxxx-xx-xxTxx:xx (-x)	xxxxxxxxxxx	xxxx-xx-xxTxx:xx (-x)	xxxxxxxxxxx
xxx	xxxxxxxxxxxxxxxxx	xxxx-xx-xxTxx:xx (-x)	xxxxxxxxxx	xxxx-xx-xxTxx:xx (-x)	xxxxxxxxxxx	xxxx-xx-xxTxx:xx (-x)	xxxxxxxxxxx

Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

Note: Include serum FSH test result as shown for those subjects who present data.

Listing 16.2.9: General Comments
Safety Population

Subject	Comment Reference	Comment
xxx	xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx