

## Guide to Analysis Data

Study XYZ-1234 is a pharmacokinetic study titled “A Phase I, Randomized, Multiple Dose, Placebo Controlled, Two-way Crossover Study to Assess the Effect of Food on the Bioavailability of the Study Treatment in Healthy Adult Subjects.”

This document provides an introduction to analysis datasets that benefit from additional explanation beyond what is available in the Data Definitions (define.pdf) document.

### Contents

<b>Guide to Analysis Data</b> .....	<b>1</b>
<b>Contents</b> .....	<b>1</b>
<b>Where to Find Key Data</b> .....	<b>2</b>
Demographics, Populations and Compliance .....	2
Safety .....	2
Pharmacokinetics .....	2
Efficacy .....	2
<b>Overview of Analysis Datasets</b> .....	<b>2</b>
ADAE – Adverse Events Analysis .....	2
ADAESUM – Adverse Events Subject Summary Analysis .....	2
ADCM – Concomitant Medications Analysis .....	2
ADPC – PK Sample Concentration Analysis .....	3
ADLB – Laboratory Tests Results Analysis.....	3
ADPK – PK Results Analysis.....	3
ADDV – Protocol Deviations Analysis .....	3
ADSL – Subject-Level Analysis Dataset.....	3
ADVS – Vital Signs Analysis.....	4

## ***Where to Find Key Data***

### **Demographics, Populations and Compliance**

The ADSL (Subject Level Analysis) dataset contains all the subject-level variables for demographics, subject characteristics, population flags and stratification variables. Information on protocol deviations is in the ADPROTV (Protocol Violations Analysis) dataset.

### **Safety**

Key safety data are found in the ADAE (Adverse Events Analysis), ADAESUM (Adverse Events Subject Summary Analysis), ADLB (Laboratory Tests Results Analysis), ADCM (Concomitant Medications Analysis) and ADVS (Vital Signs Analysis) datasets.

### **Pharmacokinetics**

Plasma concentration results are found in ADCONC (PK Sample Concentration Analysis) and summary statistics used to describe these results are in ADPK (PK Results Analysis) datasets.

### **Efficacy**

Efficacy data was not collected under this protocol.

## ***Overview of Analysis Datasets***

### **ADAE – Adverse Events Analysis**

Contains one record per reported event per subject. Its primary data source is the SDTM AE (Adverse Events) domain. ADAE contains all the observations from the AE dataset. Subjects who did not report any AEs do not appear in this dataset.

### **ADAESUM – Adverse Events Subject Summary Analysis**

Contains one record per subject. Its primary data source is ADaM ADAE (Adverse Events Analysis) dataset. ADAESUM contains all subjects from ADAE with total numbers of AEs in the study.

### **ADCM – Concomitant Medications Analysis**

Contains one record per medication per start date per subject. Its primary data source is the SDTM CM (Concomitant Medications) domain. Subjects who did not report any medication use do not appear in this dataset.

**ADPC – PK Sample Concentration Analysis**

Contains one record per pk sample per subject. Its primary data source is SDTM PC (Pharmacokinetic Concentrations) domain.

**ADLB – Laboratory Tests Results Analysis**

Contains one record per analyte per sample per subject. Its primary data source is SDTM LB (Laboratory Assessments) domain and is similar to that dataset in structure and content.

**ADPK – PK Results Analysis**

Contains one record per PK test per pk analyte per subject. Its primary data source is SDTM PP (Pharmacokinetic Parameters) domain.

**ADDV – Protocol Deviations Analysis**

The ADPROTV dataset identifies occurrences of sponsor-defined protocol deviations. A sponsor-defined list of deviations was specified for this study. The following table summarizes the categories of deviations that were investigated to populate this dataset.

**Table 1: Protocol Violations Definitions**

Study Period	Category	Description of Deviation
Pre-Treatment	Drug Screen	Positive Drug Screen
	Study Entry Criteria	<i>Each individual criterion is its own description</i>
On-Treatment	Study Drug Dosing	Patient did not take proper initial dose of study drug
	PK Assessments	PK Labs not drawn in proper window
	Prohibited Concomitant Medications	Anti-coagulant medication taken

**ADSL – Subject-Level Analysis Dataset**

The ADSL (Subject Level Analysis) dataset is the key subject-level dataset, with one record per enrolled subject. It contains all the subject-level variables for demographics, subject characteristics, disease characteristics, population flags and stratification variables. There are 10 variables from this dataset that are duplicated on the other analysis datasets. These include:

SITEID	Study Site Identifier
ITT	Safety Population flag

COMPLT	Completers Flag
BRTHDT	Date of Birth (N)
STRTDT	Start Date of Treatment
AGE	Age
SEX	Sex
RACE	Race
TRT	Actual Treatment Group
TRTN	Actual Treatment Group (N)

**ADVS – Vital Signs Analysis**

Contains one record per vital sign measurement per visit per subject. This dataset is based on the SDTM VS (Vital Signs) domain and is similar to that dataset in structure. It contains records only for subjects who had records in the SDTM VS domain.