Guide to SDTM Tabulations 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."

Screen failures are excluded from this database but are accounted for separately in the Clinical Study Report.

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

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Where to Find Key Data

Demographics and Compliance

Basic data on subject demographics and overall eligibility are in the DM (Demographics) and SC (Subject Characteristics) domains.

The special-purpose datasets SE (Subject Elements) and SV (Subject Visits) provide the start and end dates and rules for subjects entering into each study element and visit described in the Trial Design Model datasets.

Exposure to Study Treatment

Exposure data in the EX (Exposure) domain is derived from dispensing information in DA (Drug Accountability. Each record represents the estimated mean daily dose for a continuous dosing interval. See the derivation description below for more details.

Administrative information on the drug label is also recorded in DA.

Subject Disposition

The DS (Subject Disposition) domain presents an accounting of the basic subject disposition events, including informed consent, study enrollment, and either study completion or study withdrawal.

Safety

Key safety data are found in the AE (Adverse Events), LB (Laboratory Assessments), CM (Concomitant Medications), XP (Concurrent Procedures/Therapies), MH (Medical History), and VS (Vital Signs) domains.

Safety domains EG (ECG) and PE (Physical Examination) include only screening results used to qualify subjects for enrollment. SU (Substance use) includes history of alcohol and tobacco use, Urine drug screen results are found in LB.

Pharmacokinetics

Plasma concentration results are found in PC (Pharmacokinetic Concentrations) and summary statistics used to describe these results are in PP (Pharmacokinetic Parameters).

Efficacy

Efficacy data was not collected under this protocol.

Trial Design Model Datasets

Trial-level information is found in the SDTM special-purpose datasets TI (Trial Inclusion/Exclusion Criteria), TS (Trial Summary), TA (Trial Arms), TE (Trial Elements), and TV (Trial Visits).

TI contains a complete list of the study Inclusion and Exclusion criteria. This list is repeated in the Data Definitions document (define.xml), where the IETESTCD link goes to a code list that contains the short name and the full verbatim expression for each criterion.

TS contains a list of CDISC standard data elements used to describe population, intervention, and design of the study.

TA, TE, and TV all contain information about data elements used to describe the planned time periods of the study, including Arm, Element, and Visit.

Domains not Submitted

IE – Inclusion/Exclusion Criteria Not Met

The IE domain is used to record exceptions to inclusion or exclusion criteria for subjects who were enrolled into the study. This study had no inclusion/exclusion criteria exceptions, which resulted in no records being added to the IE dataset. SDTM rules stipulate that empty datasets are not submitted, hence there is no IE domain for this study.

Overview of Custom Domains

XP Concurrent Procedures/Therapies

Observation class: Interventions

This domain contains information about diagnostic, therapeutic, or surgical procedures done from the time of consent through the end of the study.

ZD Disease Characteristics

Observation class: Findings

This domain contains baseline disease characteristics and risk factors, including family history.

Derived Domains

EX – Exposure to Study Treatment

Observation class: Interventions

The EX domain is derived from data collected on the Drug Accountability CRF, which records information about routine drug dispensing, dose reductions, and drug holidays. The periods of continuous dosing in EX were estimated by establishing a "treatment period" from drug dispensing and collection dates, then adjusting the period based on information about dose reductions and drug holidays.

The dose reduction and drug holiday records often overlap in time with the treatment period and with each other. In cases where records overlap in time, a dose reduction record supersedes the routine drug dispensing record, and a drug holiday record supersedes all other records.

Dose amounts were calculated from the estimated total dose for the period, adjusted by the dose reduction record, if any, and divided by the number of days in the continuous dosing period. All dose amounts in the EX dataset therefore represent the subject's estimated mean daily dose for the period indicated by EXSTDTC and EXENDTC.

All doses were administered as a single capsule containing one of two dose levels of the study drug, or placebo. The EXTRT variable in the dataset indicates the type of capsule the subject was randomized to.

DV – Protocol Deviations

Observation class: Events

The DV dataset identifies occurrences of both sponsor-defined and investigator reported protocol deviations. The following table summarizes the categories of sponsor-defined deviations that were investigated to populate this dataset.

Study Period	Category	Description of Deviation
Pre-Treatment	Urine Drug Screen	Positive Drug Screen
	Inclusion/Exclusion Criteria	Inclusion/Exclusion Criteria not met. *These would be reported in the IE domain, but none were reported.*
On-Treatment	Study Drug Dosing	Patient did not take proper initial dose of study drug
	PK Assessments	PK Labs not drawn within specified date window
	Prohibited Concomitant Medications	Anti-coagulant medication taken