

Clinical Study Data Reviewer's Guide

SDRG, Inc.

Study ABC123

cSDRG Template Version 2018-11-01

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1. Introduction

1.1 Purpose

This document provides context for tabulation datasets and terminology that benefit from additional explanation beyond the Data Definitions document (define.xml). In addition, this document provides a summary of SDTM conformance findings.

1.2 Acronyms

Acronym	Translation
aCRF	Annotated Case Report Form
eCRF	Electronic Case Report Form
eDT	Electronic Data Transfer (e.g. central lab data, ECG vendor data, PK data, etc.)

1.3 Study Data Standards and Dictionary Inventory

Standard or Dictionary	Versions Used
SDTM	SDTM v1.2/SDTM IG v3.1.2
Controlled Terminology	CDISC SDTM CT as of 01Mar02010 plus sponsor defined
Data Definitions	define.xml v1.0
Medications Dictionary	WHODRUG June 2011
Medical Events Dictionary	MedDRA v14.1

2. Protocol Description

2.1 Protocol Number and Title

Protocol Number: ABC123

Protocol Title: PHASE I, SINGLE DOSE, OPEN-LABEL, DOSE ESCALATION PHARMACOKINETICS STUDY OF NEWDRUG IN HEALTHY SUBJECTS

Protocol Versions: All subjects participated under the original protocol. There were no amendments.

2.2 Trial Design Datasets

Are Trial Design datasets included in the submission? Yes

2.2.1. TI – Trial Inclusion/Exclusion Criteria

See [Appendix I: Inclusion/Exclusion Criteria](#) for complete text of criteria.

3. Subject Data Description

3.1 Overview

Are the submitted data taken from an ongoing study? No

Were the SDTM datasets used as sources for the analysis datasets? Yes

Do the submission datasets include screen failures? No

Were any domains planned, but not submitted because no data were collected? Yes

If yes, list domains not submitted:

IE – All subjects met inclusion/exclusion criteria.

SUPPDM – For all subjects, race was one of those pre-specified on the CRF. Specification for “other” race was not needed.

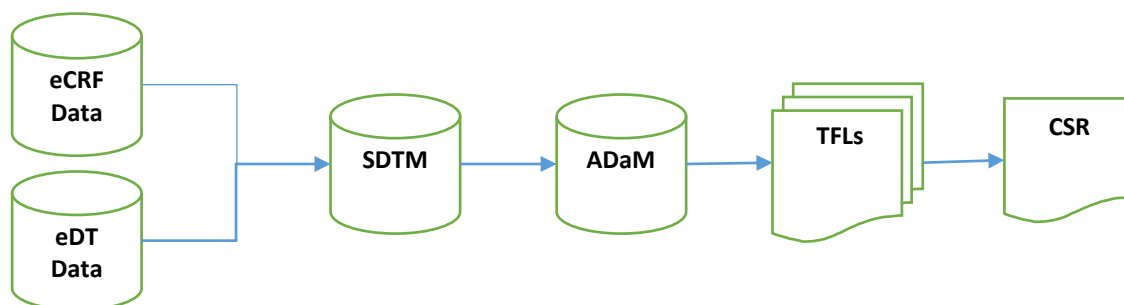
Are the submitted data a subset of collected data? No

Is adjudication data present? Yes

If yes, describe the implementation approach and location of the adjudication data:

Primary cause of death was adjudicated by the subject's primary care physician. Death details are located in the Death Details domain.

3.2 Traceability Flow Diagram



3.3 Annotated CRFs

Collected fields that have not been tabulated have been annotated as “Not Mapped”. SDRG Inc. collects certain data elements to facilitate operational processes including data cleaning and dynamically creating additional forms in the electronic data capture system. All fields that have been annotated as “Not Mapped” meet this criterion.

Explanation of data fields [Not Submitted]

aCRF page Number(s)	Data Collection Field	Explanation of why [NOT SUBMITTED]
5	Were there any product complaints?	For internal use only.
30	PI Signature Date	Not needed for analysis.

3.4 SDTM Subject Domains

Dataset – Dataset Label	Efficacy	Safety	Other	Custom	SUPP-	Related Using RELREC
AE – Adverse Events		X			X	
CM – Concomitant Medications		X			X	
CO - Comments			X			
DD – Death Details			X			
DM – Demographics			X			
DS – Disposition			X			
DV – Protocol Deviations			X			
EG – ECG Test Results		X				
EX – Exposure			X			
IE – Inclusion/Exclusion Criteria Not Met			X			
LB – Laboratory Test Results		X			X	
MH – Medical History			X			
PC – Pharmacokinetic Concentrations	X					
PE – Physical Examination		X				

Dataset – Dataset Label	Efficacy	Safety	Other	Custom	SUPP-	Related Using RELREC
PP – Pharmacokinetic Parameters	X					
SE – Subject Elements			X			
SV – Subject Visits			X			
VS – Vital Signs		X				

3.4.1. AE – Adverse Events

QNAM	Description
AELLT	MedDRA Lowest Level Term
AELLTCD	MedDRA Lowest Level Term Code
AEPTCD	MedDRA Preferred Term Code
AEHLT	MedDRA High Level Term
AEHLTCD	MedDRA High Level Term Code
AEHLGT	MedDRA High Level Group Term
AEHGLTCD	MedDRA High Level Group Term Code

3.4.2. CM – Concomitant Medications

QNAM	Description
CMLVL1CD	Preferred ATC Class Level 1 Code
CMLVL1	Preferred ATC Class Level 1 Term
CMLVL2CD	Preferred ATC Class Level 2 Code
CMLVL2	Preferred ATC Class Level 2 Term
CMLVL3CD	Preferred ATC Class Level 3 Code
CMLVL3	Preferred ATC Class Level 3 Term
CMLVL4CD	Preferred ATC Class Level 4 Code
CMLVL4	Preferred ATC Class Level 4 Term

3.4.3. LB – Laboratory Test Results

Controlled terminology codelist for LBTEST and LBTESTCD is extensible. One additional code exists in LB and XL:

- LBTESTCD BIOTINIDASE
- LBTEST Biotinidase

This test allows for detection of disease-causing mutations in affected patients which will have an impact on treatment regimine selected.

QNAM	Description
LBCLSIG	Clinical significance indicator collected on the CRF

4. Data Conformance Summary

4.1 Conformance Inputs

Was a validator used to evaluate conformance? No

Were sponsor-defined validation rules used to evaluate conformance? No

Were the SDTM datasets evaluated in relation to define.xml? Yes

Was define.xml evaluated? Yes

Provide any additional compliance evaluation information:

SDTM datasets and define.xml were loaded and checked using WebSDM version 3.0 Build 185. No structural errors were found.

4.2 Issues Summary

Dataset	Diagnostic Message	Severity	Count	Explanation
LB	Observation date must be <= latest disposition date	Low	5	Follow-up lab results with date after last visit were reported for one subject.

4.3 Additional Conformance Details

There are no additional details to be documented.

Appendix I: Inclusion/Exclusion Criteria

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion
ABC123	INCLUSION	IN01	Males, between 18 years and 55 years of age, inclusive.
ABC123	INCLUSION	IN02	Able to comprehend and willing to sign an ICF after the nature of the study has been explained.
ABC123	INCLUSION	IN03	In good health, determined by no clinically significant findings from medical history, 12-lead ECG, clinical laboratory measurements, and vital signs.
ABC123	INCLUSION	IN04	Body mass index within 18 kg/m ² to 32 kg/m ² , inclusive.
ABC123	INCLUSION	IN05	Non-tobacco users, who have not used nicotine or nicotine-containing products for at least 1 year.
ABC123	INCLUSION	IN06	Clinical laboratory evaluations including Chem-20 and CBC within the reference range for the test laboratory, unless deemed not clinically significant by the Investigator.
ABC123	INCLUSION	IN07	Negative test for selected drugs of abuse and breathalyzer alcohol test at Screening and at Day -1 (Check-in); negative cotinine test at Day -1 only.
ABC123	INCLUSION	IN08	Negative hepatitis panel (including HBsAg and anti-HCV) and negative HIV antibody screens.
ABC123	EXCLUSION	EX01	Significant history or clinical manifestation of any significant metabolic, allergic, dermatological, hepatic, renal, hematological, pulmonary, cardiovascular, gastrointestinal, neurological, or
ABC123	EXCLUSION	EX02	History of hypersensitivity reaction to the study drug or related compounds.

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion
ABC123	EXCLUSION	EX03	History of stomach or intestinal surgery or resection that would potentially alter absorption and/or excretion of orally administered drugs (appendectomy and hernia repair will be allowed).
ABC123	EXCLUSION	EX04	History or presence of an abnormal ECG unless deemed not clinically significant by both PI and Sponsor.
ABC123	EXCLUSION	EX05	Alcohol abuser defined as a history of more than 4 drinks daily (1 drink = 12 ounces of beer, 1.5 ounces of 80-proof alcohol, or 6 ounces of wine) within 1 year prior to Screening.
ABC123	EXCLUSION	EX06	Use of any tobacco or nicotine-containing products including but not limited to cigarettes, pipes, cigars, chewing tobacco, nicotine patches, nicotine lozenges, or nicotine gum within 1 year prior to
ABC123	EXCLUSION	EX07	Known or suspected use of illicit drugs within the last year.
ABC123	EXCLUSION	EX08	Use of any medication on a chronic basis.
ABC123	EXCLUSION	EX09	Participation in any other investigational study drug trial in which receipt of an investigational study drug occurred within 30 days or 5 half-lives prior to Screening, whichever is longer.