Study Data Reviewer's Guide

<Sponsor Name>

Study <Protocol Number>

Study Data Reviewer's Guide

Contents

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

1.3 Study Data Standards and Dictionary Inventory

Standard or Dictionary	Versions Used
SDTM	
Controlled Terminology	
Data Definitions	
Medications Dictionary	
Medical Events Dictionary	
Other standards (optional)	

2. Protocol Description

2.1 Protocol Number and Title

Protocol Number:

Protocol Title:

Protocol Versions:

(Note here changes in protocol amendments that affected data collection or interpretation)

2.2 Protocol Design

(Graphic or text here, or delete this section)

2.3 Trial Design Datasets

Are Trial Design datasets included in the submission?

(If no, delete the remainder of this section. If yes, refer to SDRG Completion Guidelines Section 2.3 and provide additional information below.)

2.3.1 TA – Trial Arms

(Text here)

2.3.2 TE – Trial Elements

(Text here)

2.3.3 TV – Trial Visits

(Text here)

2.3.4 TI – Trial Inclusion/Exclusion Criteria

(If criteria are not fully described in TI, complete Appendix I: Inclusion/Exclusion Criteria or hyperlink to the pages in blankcrf.pdf that contain the full criteria text. Delete these instructions.)

2.3.5 TS – Trial Summary

(Text here)

3. Subject Data Description

3.1 Overview

Are the submitted data taken from an ongoing study?

If yes, describe the data cut or database status:

(Text here)

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

If no, what were the sources of analysis datasets?

(Text here)

Do the submission datasets include screen failures?

If yes, which datasets include screen failure data?

(Text here)

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

If yes, list domains not submitted:

(Text here)

Are the submitted data a subset of collected data?

If yes, describe the reason that all collected data were not provided:

(Text here)

Additional Content of Interest

(See SDRG Completion Guidelines for additional content of interest, and include text here).

3.2 Annotated CRFs

(Text here)

3.3 SDTM Subject Domains

Dataset – Dataset Label	Efficacy	Safety	Other	SUPP-	Related Using RELREC	Observation Class
AE – Adverse Events		X				Events
DM – Demographics			X			Special Purpose
DS – Disposition			X			Events
EX – Exposure			X			Interventions

3.3.1 AE – Adverse Events

(Text and/or supplemental qualifier inventory here)

3.3.2 DS – Disposition

(Text and/or supplemental qualifier inventory here)

3.3.3 EX – Exposure

(Text and/or supplemental qualifier inventory here)

3.3.4 Dataset – Dataset Label

(Text here)

QNAM	Description

4. Data Conformance Summary

4.1 Conformance Inputs

Was OpenCDISC used to evaluate conformance?

If yes, specify the versions of OpenCDISC and the OpenCDISC validation rules:

(Text here)

Were sponsor-defined validation rules used to evaluate conformance?

If yes, describe any significant sponsor-defined validation rules:

(Text here)

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

Was define.xml evaluated?

Provide any additional compliance evaluation information:

(Text here)

4.2 Issues Summary

Dataset	Diagnostic Message	Severity	Count	Explanation

4.3 Additional Conformance Details

(Complete table below or delete this section)

Dataset	Diagnostic Message	Severity	Count	Explanation

Appendix I: Inclusion/Exclusion Criteria

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion

Appendix II: Conformance Issues Details

(Text here or delete this section)