

Analysis Data Reviewer's Guide

<Sponsor Name>

Study <Protocol Number>

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1. Introduction

1.1 Purpose

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

1.2 Acronyms

Acronym	Translation

1.3 Study Data Standards and Dictionary Inventory

Standard or Dictionary	Versions Used
SDTM	
ADaM	
Controlled Terminology	
Data Definitions	
Other standards (optional)	

1.4 Source Data Used for Analysis Dataset Creation

(insert your text here)

2. Protocol Description

2.1 Protocol Number and Title

Protocol Number:

Protocol Title:

Protocol Versions:

(Note changes in protocol amendments that affected data analysis)

2.2 Protocol Design in Relation to ADaM Concepts

(Graphic or text here to describe how the definition of standard ADaM variables for treatment, analysis period, analysis phase, etc relate to the design of the protocol)

3. Analysis Considerations Related to Multiple Analysis Datasets

3.1 Comparison of SDTM and ADaM Content

- Are data for screen failures, including data for run-in screening (for example, SDTM values of ARMCD='SCRNFIL', or 'NOTASSGN') included in ADaM datasets?

<insert text here>

- Are data taken from an ongoing study?

<insert text here>

Additional Content of Interest

<See ADRG Completion Guidelines for additional content of interest, and include text here or remove this text >.

3.2 Core Variables

Core variables are those that are represented across all/most analysis datasets.

Variable Name	Variable Description
USUBJID	Unique subject identifier
STUDYID	Study identifier used for this protocol

3.3 Treatment Variables

ARM versus TRTxxP

- Are the values of ARM equivalent in meaning to values of TRTxxP?

ACTARM versus TRTxxA

- If TRTxxA is used, then are the values of ACTARM equivalent in meaning to values of TRTxxA?

Use of ADaM Treatment Variables in Analysis

- Are both planned and actual treatment variables used in analyses?

3.4 Subject Issues that Require Special Analysis Rules

(insert your text here)

3.5 Use of Visit Windowing, Unscheduled Visits, and Record Selection

- Was windowing used in one or more analysis datasets?
- Were unscheduled visits used in any analyses?

Additional Content of Interest

<See ADRG Completion Guidelines for additional content of interest, and include text here or remove this text >.

3.6 Imputation/Derivation Methods

- If date imputation was performed, were there rules that were used in multiple analysis datasets?

(insert your text here)

Additional Content of Interest

<See ADRG Completion Guidelines for additional content of interest, and include text here or remove this text >.

4. Analysis Data Creation and Processing Issues

4.1 Split Datasets

(insert your text here)

4.2 Data Dependencies

(insert your text here)

4.3 Intermediate Datasets

(insert your text here)

4.4 Variable Conventions

(insert your text here)

5. Analysis Dataset Descriptions

5.1 Overview

- Do the analysis datasets support all protocol- and statistical analysis plan-specified objectives?

Include all objectives listed in the protocol or SAP which are not supported in the analysis datasets and the reason for their absence.

Additional Content of Interest

(See ADRG Completion Guidelines for additional content of interest, and include text here or remove this text).

5.2 Analysis Datasets

Dataset Dataset Label	Class	Efficacy	Safety	Baseline or other subject characteristics	PK/PD	Primary Objective	Structure
ADSL Subject Level Analysis Dataset	ADSL			X			One observation per subject

5.2.1 ADSL – Subject Level Analysis Dataset

(insert your text here)

5.2.x Dataset – Dataset Label

(A new section is required for each dataset that is hyperlinked in the inventory table. This section should be copied to create a new section for each dataset. The text in the section header above must be edited to match the dataset name and label.

Note that the header numbering in this section is NOT automatic. The header number for each dataset must be manually edited.)

6. Data Conformance Summary

6.1 Conformance Inputs

- Were the analysis datasets evaluated for conformance with CDISC ADaM Validation Checks?

If yes:

- Version of CDISC ADaM Validation Checks:
- Specify software used:
 - OpenCDISC
 - Sponsor-defined
 - Other (describe)
- Were the ADaM datasets evaluated in relation to define.xml?
- Was define.xml evaluated?

6.2 Issues Summary

(insert your text here and/or use following table)

Dataset(s)	Diagnostic Message and/or Check ID	Severity	Count/ Issue Rate	Explanation

7. Submission of Programs

(insert your text here)

8. Appendix

(insert text here or remove this section)