Analysis Data Reviewer’s Guide

<Sponsor Name>

Study <Protocol Number>

ADRG Template Version ccyy-mm-dd

**Analysis Data Reviewer’s Guide**

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# Introduction

## Purpose

This document provides context for the analysis datasets and terminology that benefit from additional explanation beyond the Data Definition document (define.xml) for an invididual study. In addition, this document provides a summary of ADaM conformance findings. <Also included are details regarding <legacy analysis data conversion to ADaM> < legacy tabulation data conversion to SDTM and then to ADaM>.

## Acronyms

| **Acronym** | **Translation** |
| --- | --- |
| aCRF | Annotated Case Report Form |
| ADaM | Analysis Dataset Model |
| ADRG | Analysis Data Reviewer’s Guide |
| eCRF | Electronic Case Report Form |
| eDT | Electronic Data Transfer (e.g. central lab data, ECG vendor data, PK data, etc.) |
| IG | Implementation Guide |
| NA | Not Applicable |
| SDTM | Study Data Tabulation Model |
| TAUG | Therapeutic Area User Guide |

## Study Data Standards and Dictionary Inventory

| **Standard or Dictionary** | **Versions Used** |
| --- | --- |
| SDTM |  |
| SDTM Controlled Terminology |  |
| ADaM |  |
| ADaM Controlled Terminology |  |
| Data Definitions |  |
| TAUG (if applicable) |  |
| Medications Dictionary |  |
| Medical Events Dictionary | Initial:  Final: |
| Other standards (optional) |  |

## Source Data Used for Analysis Dataset Creation

(insert your text here)

Include the following text if applicable: Please refer to the Legacy Data Conversion Plan and Report Appendix for additional details.

# Protocol Description

## Protocol Number and Title

Protocol Number:

Protocol Title:

Protocol Versions:

(Note changes in protocol amendments that affected data analysis)

## Protocol Design in Relation to ADaM Concepts

(Graphic, table, 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)

# Analysis Considerations Related to Multiple Analysis Datasets

## Core Variables

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

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

## Treatment Variables

ARM versus TRTxxP

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

<Yes/No> (insert additional text here or a mapping table or a figure)

ACTARM versus TRTxxA

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

<Yes/No> (insert additional text here or a mapping table or a figure)

Use of ADaM Treatment Variables in Analysis

Are both planned and actual treatment variables used in analysis?

<Yes/No> (insert additional text here or a mapping table or a figure)

Use of ADaM Treatment Grouping Variables in Analysis

Are both planned and actual treatment grouping variables used in analysis?

<Yes/No> (insert additional text here or a mapping table or a figure)

## Subject Issues that Require Special Analysis Rules

(insert your text here or indicate that there were no subject issues to be documented)

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

Was windowing used in one or more analysis datasets?

<Yes/No> (insert additional text here)

Were unscheduled visits used in any analyses?

<Yes/No> (insert additional text here)

Additional Content of Interest

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

## Imputation/Derivation Methods

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

<Yes/No> (insert additional text here)

Additional Content of Interest

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

# Analysis Data Creation and Processing Issues

## Split Datasets

(insert your text or table here or indicate there are no split datasets)

## Data Dependencies

(insert your text here or indicate there are no data dependencies)

## Intermediate Datasets

(insert your text here or indicate there are no intermediate datasets)

# Analysis Dataset Descriptions

## Overview

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

<Yes/No> <insert additional text here>

Are data taken from an ongoing study?

<Yes/No> <insert additional text here>

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

<Yes/No> (insert additional text here)

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).

## Analysis Datasets

| **Dataset Dataset Label** | **Class** | **Efficacy** | **Safety** | **Baseline or other subject characteristics** | **PK/PD** | **Primary Objective** | **Structure** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| [ADSL](#_5.2.1_ADSL_–)  Subject Level Analysis Dataset | ADSL |  |  | X |  |  | One observation per subject |
|  |  |  |  |  |  |  |  |

### 5.2.1 ADSL – Subject Level Analysis Dataset

(insert your text here)

(insert date imputation rules if applicable)

### 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.**)

# Data Conformance Summary

## Conformance Inputs

Specify the software name and version for the analysis datasets

(Text here)

Specify the version of the validation rules (i.e. CDISC, FDA) for the analysis datasets

(Text here)

Specify the software name and version for the define.xml

(Text here)

Specify the version of the validation rules (i.e. CDISC, FDA) for the define.xml

(Text here)

Provide any additional compliance evaluation information:

(Text here)

## Issues Summary

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

| **Dataset** | **Diagnostic Message** | **Severity** | **Count** | **Explanation** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

# Submission of Programs

All programs for analysis datasets and primary and secondary efficacy results are submitted. They were all created on a <text here> platform using <version>. The internal reference date used to create dates in ADaM datasets is <date>.

## ADaM Programs

| **Program Name** | **Output** | **Macro Used** |
| --- | --- | --- |
|  |  |  |

## Analysis Output Programs

| **Program**  **Name** | **Output**  **Number** | **Title** | **Input** |
| --- | --- | --- | --- |
|  |  |  |  |

## Macro Programs

| **Program**  **Name** | **Purpose** |
| --- | --- |
|  |  |

# Appendix

(insert text here or remove this section)

|  |
| --- |
| Legacy Data Conversion Plan and Report Appendix |

# Purpose

The purpose of this appendix is to document the traceability of key output analysis results with ADaM when the analysis results were generated using a legacy process.

Because of transformations required during ADaM conversion, some of the terms, categories and data formats used in the tabulation data have been translated into CDISC standard formats in the ADaM data.  This appendix identifies differences between the legacy analysis and ADaM data, and explains how ADaM represents the equivalent data.

# Conversion Data Flow

The legacy data was converted to SDTM/ADaM as described in the following data flow diagram.

**Rationale:**

(Text here)

# Converted Data Summary

## Issues Encountered and Resolved

* (Text and/or table here)
* (Text and/or table here)

# Traceability Data Flow

The legacy data traceability from collection to submission is described in the following data flow diagram.

# Outstanding Issues

* (Text and/or table here)
* (Text and/or table here)