Integrated

Analysis Data Reviewer’s Guide

<Sponsor Name>

<Compound Name>

<Type of Integration>

<iADRG Version x.x>

iADRG Template Version yyyy-mm-dd

**Integrated Analysis Data Reviewer’s Guide**

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# Introduction

## Purpose

This document provides context for the integrated analysis datasets and terminology that benefit from additional explanation beyond the Data Definitions document (Define-XML) for integrated studies and a summary of integrated analysis data conformance findings. <Also included are details regarding any legacy data conversion that was done within the integration.>

## Acronyms

| **Acronym** | **Definition** |
| --- | --- |
| ADaM | Analysis Dataset Model |
| ADRG | Analysis Data Reviewer’s Guide |
| iADRG | Integrated Analysis Data Reviewer’s Guide |
| DBL | Database Lock |
| IG | Implementation Guide |
| NA | Not Applicable |
| SDTM | Study Data Tabulation Model |
| TAUG | Therapeutic Area User Guide |

## Data Standards and Dictionary Inventory for Integrated Datasets

| **Standard or Dictionary** | **Versions Used** |
| --- | --- |
| SDTM Controlled Terminology |  |
| ADaM |  |
| ADaM Controlled Terminology |  |
| Data Definitions |  |
| TAUG |  |
| Medications Dictionary |  |
| Medical Events Dictionary |  |
| Other Standards |  |

**Additional Content of Interest**

(See the iADRG Completion Guidelines for additional content of interest. If applicable, document here all character sets used in the data other than ASCII.)

## Source Data Used for Integrated Analysis Dataset Creation

(Insert your text here: data sources for each study for data used for pooling.)

| **Study Identifier (STUDYID)** | **Protocol Number** | **Source Data Standard** | **Cutoff-Date or DBL-Date / Study Status** |
| --- | --- | --- | --- |
|  |  | SDTM Model/IG <version>  Legacy Tabulation  Legacy Analysis  ADaM Model/IG <version> | 01-20-2021/Ongoing |
|  |  |  |  |

**Additional Content of Interest**

(See the iADRG Completion Guidelines for additional content of interest.)

## Traceability Flow Diagram

(Insert flow diagram and details as needed here.)

# Description of Protocols Used in the Integrated Datasets

## Protocol Numbers and Titles

| **Protocol Number** | **Indication(s)/Protocol Title** | **Phase** | **Treatment ARM(s)** |
| --- | --- | --- | --- |
|  |  |  | <compound, placebo, and/or competitor.> |
|  |  |  |  |

**Additional Content of Interest**

(See the iADRG Completion Guidelines for additional content of interest. Any treatments from one or more protocols which were not included in the integration should be documented here.)

## Integrated Analysis Strategy and Design in Relation to ADaM Concepts

(Insert a graphic, a table or text here to describe the integration plan and how the definition of standard ADaM variables for treatment, analysis period, analysis phase, etc. relate to the design of the analysis integration.)

# Analysis Considerations Related to Integrated Analysis Datasets

## Core Variables

Core variables are those that are represented across all integrated analysis datasets.

| **Variable Name** | **Variable Description** |
| --- | --- |
| STUDYID | Study identifier used for this protocol |
| USUBJID | Unique subject identifier |
| <core variable> | <variable description> |

## Treatment Variables

ARM versus TRTxxP

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

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

Use of Treatment Variables in Integrated Analysis

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

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

Use of Treatment Grouping Variables in Integrated Analysis

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

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

**Additional Content of Interest**

(See the iADRG Completion Guidelines for additional content of interest.)

## Subject or Protocol Considerations that Require Special Integrated Analysis Rules

Were any additional updates (e.g. codelists, value-level metadata, dictionaries) performed when integrating?

<Yes/No> (Insert additional text here or a table or a figure.)

**Additional Content of Interest**

(See the iADRG Completion Guidelines for additional content of interest.)

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

Was windowing used in one or more integrated analysis datasets?

<Yes/No> (Insert additional text here.)

Were unscheduled visits included in any integrated analysis datasets?

<Yes/No> (Insert additional text here.)

Were rules used for record selection in one or more integrated analysis datasets?

<Yes/No> (Insert additional text here.)

**Additional Content of Interest**

(See the iADRG Completion Guidelines for additional content of interest.)

## Imputation/Derivation Methods

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

<Yes/No> (Insert additional text here.)

**Additional Content of Interest**

(See the iADRG Completion Guidelines for additional content of interest.)

# Integrated 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 or visual here or indicate there are no data dependencies.)

## Intermediate Datasets

(Insert your text or table here or indicate there are no intermediate datasets.)

**Additional Content of Interest**

(See the iADRG Completion Guidelines for additional content of interest.)

# Integrated Analysis Dataset Descriptions

## Overview

Is an integrated statistical analysis plan included in the submission?

<Yes/No> (Insert additional text here.)

Do the integrated datasets support all integrated statistical analysis plan specified objectives?

<Yes/No/Not Applicable>

(Include all objectives of the integrated analyses listed in the integrated statistical analysis plan which are not supported in the integrated analysis datasets and the reason for their absence.)

**Additional Content of Interest**

(See the iADRG Completion Guidelines for additional content of interest.)

## Integrated Analysis Datasets

| **Dataset Name Dataset Label** | **Class** | **Efficacy (E)/Safety (S)/Immunogenicity (I)** | **Baseline or Other Subject Characteristics** | **All Studies Contribute** | **Structure** |
| --- | --- | --- | --- | --- | --- |
| [ADSL](#_5.2.1_ADSL_–)  Subject-Level Analysis Dataset | ADSL |  | X | X | One record per subject |
|  |  | <E/S/I> |  |  |  |

### 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 edited manually.**)

# Data Conformance Summary

## Conformance Inputs

| **Question** | **Description** |
| --- | --- |
| Software name and version used for the integrated dataset validation |  |
| Version of the validation rules (i.e. CDISC, FDA, PMDA) for the integrated datasets |  |
| Software name and version for the Define-XML validation |  |
| Version of the validation rules (i.e. CDISC, FDA, PMDA) for the Define-XML |  |

Provide any additional compliance evaluation information:

(Text here)

## Issues Summary

(Insert your text here and/or use the following table. If any columns in the table are not applicable, then provide the reason. Do not delete the empty columns.)

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

# Submission of Programs

<All programs for the integration of analysis datasets and key <efficacy/safety> results are submitted.> <They were all created using <software> <version>>. The internal reference date used to create dates in integration of ADaM datasets is <date>.

## Integrated ADaM Programs

| **Program Name** | **Dataset** | **Macro Used** |
| --- | --- | --- |
|  |  |  |

## Integrated Analysis Output Programs

(Document if analysis results metadata (ARM) is included in the submission.)

| **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 legacy data when a conversion was done within the integration.

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

## Conversion Data Flow

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

(Refer to the 1.5 Traceability Flow Diagram section for legacy data traceability from source to submission.)

**Rationale:**

(Text here)

## Converted Data Summary

### 3.1 Issues Encountered and Resolved

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

## Outstanding Issues

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