Analysis Data Reviewer's Guide

# 1. Introduction

This document describes the analysis datasets for ABC-123.

This guide is intended to assist the reviewer in understanding the structure and content of the analysis datasets.

# 2. Protocol Description

Protocol: XYZ-001

Protocol Title: A Study to Evaluate the Efficacy and Safety of a New Drug

# 3. Analysis Datasets

The following analysis datasets are included in this submission:

- ADSL (Subject-Level Analysis Dataset)

- ADAE (Adverse Event Analysis Dataset)

# 4. Data Conformance

The analysis datasets were checked for conformance with the CDISC ADaM standard.

Any conformance issues are documented in the data definition file (define.xml).

# 5. Program and Macro Catalog

This section provides a catalog of the programs and macros used to create the analysis datasets.

- adsl.sas

- adae.sas

# 6. Data Listings

This section provides information about the data listings included in this submission.

# 7. Figures and Tables

This section provides information about the figures and tables included in this submission.