Study Data Reviewer's Guide

# 1. Introduction

This document describes the study data for ABC-123.

This guide is intended to assist the reviewer in understanding the structure and content of the study data.

# 2. Protocol Description

Protocol: XYZ-001

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

# 3. List of Included Documents

This submission includes the following documents:

- SDRG (this document)

- define.xml

- Annotated CRF

# 4. Data Collection and Processing

This section describes how the data was collected and processed.

# 5. SDTM Datasets

The following SDTM datasets are included in this submission:

- DM (Demographics)

- AE (Adverse Events)

# 6. Data Conformance

The study data were checked for conformance with the CDISC SDTM standard.

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

# 7. Appendices

This section contains any appendices.