Study Data Reviewer's Guide

Nonclinical

Study to demonstrate use of Nimort system to map non-Clinical data to SEND standard

Nimort-01

Note: The data in this sample submission package and the information/processes mentioned in this document are entirely dummy.

Nimble Clinical Research

New Jersey, USA

CONTENTS

Study to demonstrate use of Nimort system to map non-Clinical data to SEND standard 1

Nimort-01 1

1. SDRG Introduction 3
   1.1 Study Title, Number, and Version 3
   1.2 Summary of SEND Dataset Creation Process 3
   1.3 SEND Dataset Verification 3
2. Study Design 3
   2.1 Study Design Summary 3
   2.2 Trial Design Domain Overview 4
3. Standards, Formats, and Terminologies and their Versions 4
   3.1 Standards Used 4
   3.2 Rationale for Standards Selection 4
   3.3 Nonstandard Terminology 4
4. Description of Study Datasets 4
   4.1 Dataset Summary 4
   4.2 Dataset Explanation 5
   4.3 Use of Supplemental Qualifiers 5
5. Data Standards Validation Rules, Versions, and Conformance Issues 5
   5.1 Validation Outcome Summary 5
   5.2 FDA SEND Validation Rules Version 6
   5.3 Errors 6
   5.4 Warnings 6
6. Sponsor Decisions Related to Data Standard Implementations 6
   6.1 Sponsor Defined Standardization Descriptions 6
   6.2 Differences between SEND Datasets and Study Report 6
   6.3 Nonstandard Electronic Data Submitted 6
   6.4 Legacy Data Conversion 6

1. SDRG Introduction

1.1 Study Title, Number, and Version

Study Title	Study to demonstrate use of Nimort system to map non-Clinical data to SEND standard
Study Number	Nimort-01
Study Version	1

1.2 Summary of SEND Dataset Creation Process

Dummy raw datasets were created and this data was mapped to SEND standard using automated tools available in Nimort system.

1.3 SEND Dataset Verification

CDISC SEND 3.0 standards were followed and validated using in-built checks in Nimort system. Internal team reviewed the mapping and ensured all the data was mapped. Additionally analysis generated out of SEND datasets was directly reproduced using the source data.

2. Study Design

2.1 Study Design Summary

Group	Treatment	Dose Level	Dose Concentration	Dose Volume	Number of Animals	
		mg/kg/ day	mg/mL	mL/kg	Male	Female
1	Placebo	0	Not applicable	Not applicable	18	32
2	Treatment	10-20	Not available	Not available	19	31

2.2 Trial Design Domain Overview

The following diagram illustrates the trial design.

Study Group	Trial Arm		Elements in each EPOCH	Trial Set	
SPGRPCD	**ARMCD**	**ARM**	**EPOCH: Elements**	**SETCD**	**SET**
1	PLAC	Placebo	SCREENING: Screening RUN-IN: Run-in TREATMENT: Placebo FOLLOW-UP: Follow-up	1	Control Group, Vehicle Control once daily
2	TRT	Treatment	SCREENING: Screening RUN-IN: Run-in TREATMENT: Treatment FOLLOW-UP: Follow-up	2	Low-Dose Group, 10 mg/kg Drug A once daily
				3	High-Dose Group, 20 mg/kg Drug A once daily

3. Standards, Formats, and Terminologies and their Versions

3.1 Standards Used

Standard or Dictionary	Standard or Dictionary	Versions Used
Tabulation Datasets	CDISC SEND	3.0
Controlled Terminology	CDISC SEND Controlled Terminology	2016-03-25
Data Definition file	CDISC DEFINE.XML	2.0

3.2 Rationale for Standards Selection

Latest Standards were chosen at the time of data mapping for controlled terminology. Standard for tabulation datasets and data definition file are chosen based on standard version in data standards catalog accepted by FDA.

3.3 Nonstandard Terminology

No non-standard terminology was used in mapping.

4. Description of Study Datasets

4.1 Dataset Summary

Dataset Name	Dataset Label	Supp. Qualifiers?	Related Records?	Observation Class
TA	Trial Arms			Trial Design
TE	Trial Elements			Trial Design
TS	Trial Summary			Trial Design

Dataset Name	Dataset Label	Supp. Qualifiers?	Related Records?	Observation Class
TX	Trial Sets			Trial Design
DM	Demographics			Special Purpose
POOLDEF	Pool Definition			Special Purpose
CO	Comments			Special Purpose
DS	Disposition			Events
EX	Exposure	Y		Interventions
BG	Body Weight Gains			Findings
BW	Body Weights			Findings
CL	Clinical Observations			Findings
FW	Food and Water Consumption			Findings
LB	Laboratory Tests Results			Findings
MA	Macroscopic Findings			Findings
MI	Microscopic Findings			Findings
OM	Organ Measurements			Findings

4.2 Dataset Explanation

Dataset Description can be added on need basis.

4.3 Use of Supplemental Qualifiers

Dataset Name	Associated Dataset	Qualifiers Used
EX	SUPPEX	EXTYP – Preparation Type

5. Data Standards Validation Rules, Versions, and Conformance Issues

5.1 Validation Outcome Summary

SEND data and corresponding define.xml were evaluated for compliance together via Pinnacle 21 Community tool. The issues and define.xml were resolved wherever possible. The issues which weren't resolved are described below along with detailed explanation.

5.2 FDA SEND Validation Rules Version

Rule conformance to SEND 3.0 was evaluated using Pinnacle 21 Community version 2.1.0, which includes checks for conformance against the FDA Specific SEND Validation Rules, Version 3.0.

5.3 Errors

No errors were reported.

5.4 Warnings

The following warnings were reported:

Rule	Message	Domain(s)	Count	Explanation
FDAN108	BGDTC is after BGENDTC	BG	1	The data reflects the collected data and the data could not be cleaned at the time of data packaging.
…	…	…	…	…

Note: Only one warning is presented as an example, although several more issues will show up when complete compliance checks are run.

6. Sponsor Decisions Related to Data Standard Implementations

6.1 Sponsor Defined Standardization Descriptions

Not applicable

6.2 Differences between SEND Datasets and Study Report

Not applicable

6.3 Nonstandard Electronic Data Submitted

None

6.4 Legacy Data Conversion

Not applicable