



SEND Conformance Rules Development and Documentation Guide

Version 2.0 (Final)

Prepared by the
SEND Conformance Rules Subteam

Notes to Readers

This is the final version of the Conformance Rules for the Standard for Exchange of Nonclinical Data Implementation Guide (SENDIG) Versions 3.0 and 3.1.

Revision History

Date	Version	Description of Changes
2020-12-16	2.0	Final
2020-03-10	1.0	Final

See [Appendix C](#) for Representations and Warranties, Limitations of Liability, and Disclaimers.

CONTENTS

1	INTRODUCTION	3
1.1	PURPOSE	3
1.2	SCOPE	3
1.3	METHODOLOGY FOR THE IDENTIFICATION OF SEND CONFORMANCE RULES	3
2	METHODOLOGY FOR THE VERSIONING OF SEND CONFORMANCE RULES	6
3	METHODOLOGY FOR THE REMOVAL OF SEND CONFORMANCE RULES	6
4	APPENDICES.....	7
	APPENDIX A: DEFINITIONS OF RULE SETS	7
	APPENDIX B: PLAIN LANGUAGE GUIDELINES.....	8
	APPENDIX C: REPRESENTATIONS AND WARRANTIES, LIMITATIONS OF LIABILITY, AND DISCLAIMERS	9

1 Introduction

This guide was developed by the Standard for Exchange of Nonclinical Data (SEND) Conformance Rules Subteam to explain the methodology used to create SEND conformance rules and the logic applied to determine which implementation guidance should be translated into rules. To the greatest extent possible, the creation of SEND conformance rules is consistent with the best-practice recommendations from the CDISC Conformance Rules Operational Group. Consistency in conformance rule development across the CDISC standards development community is an important part of the standards development process.

1.1 Purpose

The purpose of this guide is to provide methodology for the identification and classification of implementation text that constitutes a rule definition.

1.2 Scope

SEND conformance rules are limited to those that are associated with SEND Implementation Guide (SENDIG) text.

The following are considered to be outside the scope of SEND conformance rules:

- Rules that are not supported by a definitive statement in the SENDIG
- Business rules
- Data validation logic that is not specifically linked to Study Data Tabulation Model (SDTM) implementation guidance
- Rules that check across studies within a submission

1.3 Methodology for the Identification of SEND Conformance Rules

- SEND conformance rules are linked to a declarative or directive statement in the SENDIG.
 - **Declarative statements** do not include directive words (e.g., “1 record per subject”).
 - **Directive statements** may include “Must,” “Must not,” “Required,” “Shall,” “Shall not,” “Should,” or “Should not.”
- SEND conformance rules are identified and classified regardless of the perceived programmability of the rule.
- SEND conformance rules are not created from examples.
- For each SEND conformance rule, both a plain text and pseudo code description of the rule is created.
 - The **plain text explanation** of the rule is intended to provide an explanation of the rule that does not require familiarity with programming logic to understand.
 - The **pseudo code explanation** of the rule is intended to provide a logical statement which can be used to check compliance with the rule.

The following table provides a description of the columns used to tabulate the SEND conformance rules.

Rules Column Label	Description																				
CDISC SEND Rule ID	Identifier used to uniquely identify a SEND conformance rule																				
Class	<p>The SDTM Observation Class to which the rule applies is indicated using a 3-character abbreviation:</p> <ul style="list-style-type: none"> TDM – Trial Design Model Datasets SPC – Special Purpose Class FND – Findings Class EVT – Events Class INT – Interventions Class REL – Relationship Datasets ALL – All Classes <p>If the rule applies to multiple classes, each observation class is listed separated by commas. If the rule applies to all classes, ALL is used. If the concept of class is not applicable to the rule, NA is used.</p>																				
Domain	<p>The domain to which the rule applies is indicated using the 2-character domain abbreviation. Exceptions: RELREC, SUPP--, POOLDEF.</p> <p>If the rule applies to multiple domains, each domain abbreviation is listed separated by commas. If the rule applies to multiple domains but not all domains, this may also be indicated using logical operators (e.g., AND, OR, NOT). If the rule applies to all domains, ALL is used. If the concept of domain is not applicable to the rule, NA is used.</p>																				
Variable	<p>The variable name to which the rule applies is indicated here. If the rule applies to a variable across multiple domains, the variable name is presented with dashes in place of the domain abbreviation (e.g., --STDY, --ENDY). If the rule applies to all variables, ALL is used. If the rule applies to all variables in the General Observation Class, GEN is used. If the concept of variable is not applicable to the rule, NA is used.</p>																				
Plain Text Explanation of Condition/Rule	Provides an explanation of the rule and any applicable condition that applies to the rule. Familiarity with programming logic is not required to understand the rule. Literals are enclosed in quotation marks.																				
Condition	<p>If a rule is applied only in a conditional set of circumstances, the condition is defined in this column. The following are guidelines for composing condition statements:</p> <ul style="list-style-type: none"> The condition is not started with the word "If." Multiple parts of the condition are separated by standard logical operators (e.g., AND, OR, NOT). Controlled Terminology or terminology taken from the SENDIG is used to describe conditions or requirements in a standard way. Literals are enclosed in quotation marks. If a condition applies to each of several variables in a list, the variable list is enclosed in parenthesis and comma separated. {i.e., (Variable 1, Variable 2)} <p>The following terms and definitions are used to define rule conditions:</p> <table> <tr> <th>Term</th><th>Definition</th></tr> <tr> <td>=</td><td>Should equal, must equal, equals</td></tr> <tr> <td><=</td><td>Less than or equal to</td></tr> <tr> <td><</td><td>Less than</td></tr> <tr> <td>></td><td>Greater than</td></tr> <tr> <td>>=</td><td>Greater than or equal to</td></tr> <tr> <td>In</td><td>Must be defined in, must include</td></tr> <tr> <td>^</td><td>Not: general negation operator</td></tr> <tr> <td>^=</td><td>Not equal</td></tr> <tr> <td>First</td><td>The first instance, e.g., date (implies sorting)</td></tr> </table>	Term	Definition	=	Should equal, must equal, equals	<=	Less than or equal to	<	Less than	>	Greater than	>=	Greater than or equal to	In	Must be defined in, must include	^	Not: general negation operator	^=	Not equal	First	The first instance, e.g., date (implies sorting)
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Rule	<p>A concise and unambiguous statement of the conformance principle to be applied. Only 1 principle is stated per rule. If the rule is applied only when a specific condition is met, then the condition is specified in the Condition column.</p> <p>The following are guidelines for composing rule statements:</p> <ul style="list-style-type: none"> • All rules are stated uniquely at the highest level of hierarchy possible. • Any reference to a variable in a domain other than the object variable's domain is in the form "Domain.Variable" (e.g., TA.ARM, DM.SEX). • If a variable should be populated with a selection from a discrete list described in guidance but not in CDISC Controlled Terminology, then the syntax is "Variable in (value1, value2...)." Quotes around individual values in the list are not recommended unless the values contain special characters such as commas. • If a variable should be populated with a selection from a discrete list described in CDISC Controlled Terminology, then the syntax should be "Variable in {CT List Name}." Note the use of braces instead of parentheses • When a variable should not contain a value, use the keyword "null" (e.g., "AGETXT=null") rather than phrases like "is missing," "equals blank," or "should not be populated." • Literals are enclosed in quotation marks. • Multiple parts of the condition are separated by standard logical operators (e.g., AND, OR, NOT). • If a condition applies to each of several variables in a list, the variable list is enclosed in parenthesis and comma separated. (i.e., (Variable 1, Variable 2)). • Logical operators should be used instead of phrases such as "less than or equal to," "not greater than," "should equal," and so on. This is to enforce a concise and unambiguous rendering of the rule. <p>The following terms and definitions are used to define rules:</p> <table> <tr> <th>Term</th><th>Definition</th></tr> <tr> <td>=</td><td>Should equal, must equal, equals</td></tr> <tr> <td><=</td><td>Less than or equal to</td></tr> <tr> <td><</td><td>Less than</td></tr> <tr> <td>></td><td>Greater than</td></tr> <tr> <td>>=</td><td>Greater than or equal to</td></tr> <tr> <td>In</td><td>Must be defined in, must include</td></tr> <tr> <td>^</td><td>Not: general negation operator</td></tr> <tr> <td>^=</td><td>Not equal</td></tr> <tr> <td>First</td><td>The first instance, e.g., date (implies sorting)</td></tr> <tr> <td>Last</td><td>The last instance, e.g., date (implies sorting)</td></tr> <tr> <td>Unique</td><td>Only occurrence of value within defined scope</td></tr> </table>	Term	Definition	=	Should equal, must equal, equals	<=	Less than or equal to	<	Less than	>	Greater than	>=	Greater than or equal to	In	Must be defined in, must include	^	Not: general negation operator	^=	Not equal	First	The first instance, e.g., date (implies sorting)	Last	The last instance, e.g., date (implies sorting)	Unique	Only occurrence of value within defined scope
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	Exists	Object is present, e.g., dataset, variable (does not imply that object is populated with data)
	Null	Object does not contain data
	One-to-one	Object in isomorphic relationship with another object, i.e., value pair is unique
Cited Document	Indicates with which version of SENDIG the rule is associated (e.g., SENDIG v3.0, SENDIG v3.1)	
Cited Document Section	Indicates the SENDIG version and section/subsection that prescribes the rule. In cases where the rule is prescribed in multiple sections, only the first instance is included. If more than 1 section is cited, the citations are included in order and separated by " ".	
Cited Item	Indicates the specific location for the cited reference (e.g., Text, CDISC Notes, Domain Table Header, Assumption).	
Cited Guidance	Indicates the specific SENDIG text used to support the SEND conformance rule. If more than 1 section is cited, the citations are included in order and separated by " ".	
Release Notes	Represent free-text description identifying anything of note related to the rule. This includes additional information regarding the SEND conformance rule in relation to previous SEND conformance rule publications. Release notes are also provided if changes were not impactful (e.g., the cited guidance was updated or reformatted).	

2 Methodology for the Versioning of SEND Conformance Rules

Versions of SEND rules are indicated by adding a version number, which is a sequential integer (e.g., SEND rule 56 becomes SEND rule 56.1, SEND rule 56.2).

SEND rules are versioned when a change is made to the scope or content of the rule, as indicated by a change in the Class, Domain, Variable, Plain Text, Condition, or Rule columns. Changes to Cited Guidance which do not result in changes to the columns mentioned will not result in a new version of the SEND rule.

Some changes are significant enough to warrant removing a SEND rule and creating a new SEND rule.

3 Methodology for the Removal of SEND Conformance Rules

If a SEND rule is no longer applicable to a SENDIG version, the SEND rule will be deleted. Release notes may indicate if a SEND rule has been added with a related concept to the removed SEND rule. These notes are intended to explain the change.

4 Appendices

Appendix A: Definitions of Rule Sets

There are several types of rule sets surrounding SEND. These rules can be divided into 4 distinct categories: conformance rules, business rules, technical rejection criteria, and validation rules.

1. **Conformance rules:** Conformance rules are created and maintained by CDISC. Conformance rules describe the criteria that must be met to be in compliance with the CDISC standard.
2. **Business rules:** Business rules are created by a specific organization to describe the criteria that should be met to allow for the deliverable to be useful in the conduct of normal business practices. For example:
 - a. US Food and Drug Administration (FDA) Business Rules describe those criteria that should be met in order for datasets to be used internally for FDA business practices such as submission review.
3. **Technical rejection criteria for study data:** Technical rejection criteria describe the minimum requirements for electronic Common Technical Document (eCTD) submissions to be accepted by the agency at the gateway.
4. **Validator rules:** Validator rules are rule sets used by validation tools. Each validator can have its own set of validation rules. For example:
 - a. FDA Validator Rules describe the validation rules used by the FDA's in-house proprietary validator.
 - b. Pinnacle 21 Validator Rules describe the validation rules used by the Pinnacle 21 Validator Tool.

Rule	Owner	Published Location
Conformance Rules		
SDTM	CDISC	https://www.cdisc.org/standards/foundational/sdtmig/conformance-rules-v11-sdtmig-v32-and-v33
SEND	CDISC	https://www.cdisc.org/standards/foundational/send/conformance-rules-v1-0-sendig-v3-0
Business Rules		
FDA Business Rules	FDA	https://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm
Technical Rejection Criteria for Study Data		
eCTD Technical Rejection Criteria for Study Data	FDA	https://www.fda.gov/drugs/developmentapprovalprocess/formssubmissionrequirements/
Validator Rules		
FDA Validator Rules	FDA	https://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm
Pinnacle 21 Community	Pinnacle 21	https://www.pinnacle21.com/validation-rules/sdtm

Appendix B: Plain Language Guidelines

Rules should be written using the principles outlined in the *Federal Plain Language Guidelines* (available at <https://plainlanguage.gov/guidelines/>). These principles encourage the use of precise, simple language to ensure clear communication; for example, plain language guidelines for indicating requirements are:

Use “must” to indicate requirements

The word “must” is the clearest way to convey to your audience that they have to do something. “Shall” is one of those officious and obsolete words that has encumbered legal style writing for many years. The message that “shall” sends to the audience is, “this is deadly material.” “Shall” is also obsolete. When was the last time you heard it used in everyday speech?

Besides being outdated, “shall” is imprecise. It can indicate either an obligation or a prediction. Dropping “shall” is a major step in making your document more user-friendly. Don’t be intimidated by the argument that using “must” will lead to a lawsuit. Many agencies already use the word “must” to convey obligations. The US Courts are eliminating “shall” in favor of “must” in their Rules of Procedure. One example of these rules is cited below.

Instead of using “shall”, use:

“must” for an obligation,

“must not” for a prohibition,

“may” for a discretionary action, and

“should” for a recommendation.

Reference:

Plain Language Action and Information Network, US General Services Administration. *Federal Plain Language Guidelines*. Published March 2011; revised May 2011. Accessed July 31, 2020.
<https://plainlanguage.gov/media/FederalPLGuidelines.pdf>

Appendix C: Representations and Warranties, Limitations of Liability, and Disclaimers

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