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Single Day Event

Efficient preparation of eData (CRT package) for PMDA with PHUSE templates

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Disclaimer

- The contents of this presentation represent the opinions of the individual presenters and do not represent the opinions or positions of the organization to which they belong.

- The contents of this announcement are omitted for convenience of explanation, and may not always contain accurate information.

Agenda

- Looking back in 2022
- Form A and Reviewer's Guide
- Issue Summary Writing Guide

Agenda

- Looking back in 2022
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Looking back in 2022

- Release of White Paper
- Automatic extraction of explanation of Error issue in DRGs by R
- Review of draft iADRG created by PHUSE global
- **Form A and Reviewer's Guide**
- **Issue Summary Writing Guide**

White Paper

- The initial version of "**Best Practices for the Submission of Data in Japan**" was released on 09-Jul-2022.
- As for the FAQs, please refer to the English translation published by PMDA.
- This white paper will be revised to match the current notifications.

Agenda

- Looking back in 2022
- Form A and Reviewer's Guide
- Issue Summary Writing Guide

Form A and Reviewer's Guide

- Technical Conformance Guide* was last updated on April 1st 2022.
- Form A was last updated on June 27th 2022.
- PHUSE verified that all items discussed in Technical Conformance Guide are covered in Form A.
- Form A can now reference Reviewer's Guides in order to avoid duplicate work and/or inconsistencies between two documents.

"Technical Conformance Guide" = PMDA Technical Conformance Guide on Electronic Study Data Submissions (dated April 1, 2022)

Form A and Reviewer's Guide

Reference availability of the reviewer's guide

If all of the following information (subsequent rows in this section (section b), and section c and d) are included in the reviewer's guide, it will be acceptable to refer to the reviewer's guide.

☐ Refer to the reviewer's guide (If applicable, delete the following rows)

Insert from Form A section 4.1.1b; 000247169.pdf (pmda.go.jp)

- However, all items in subsequent sections in Form A must be included in the reviewer's guide. i.e. no partial reference to reviewer's guide is not allowed.
- PMDA provided examples of where each item on Form A might be included in the reviewer's guide. (https://www.pmda.go.jp/files/000247521.pdf)

Form A and Reviewer's Guide

- With the aid of aforementioned PMDA suggestions, PHUSE assessed each items from Form A sections 4.1.1.b, c, and d.
- We will show our recommendation on how each Form A item may be included in cSDRG and ADRG.

Template prepared by PHUSE
cSDRG : Clinical Study Data Reviewer's Guide (cSDRG) Package - WORKING GROUPS - PHUSE Advance Hub
ADRG : Analysis Data Reviewer's Guide (ADRG) Package - WORKING GROUPS - PHUSE Advance Hub

Note: English Form A is used in this presentation. However, Japanese Form A is generally used for eData submission.

Form A 4.1.1b - Standards

cSDRG

1.3 Study Data Standards and Dictionary Inventory

Standard or Dictionary	Versions Used
SDTM	
Controlled Terminology	
Data Definitions	
Medications Dictionary	
Medical Events Dictionary	
Other standards (optional)	

Form A

Standards and those versions used for creating datasets
*If the version used for the validation differs from that used for the dataset creation, for the validation in the column "Notes".

Standard	Version	Notes
SDTM SDTM IG		
ADaM ADaM IG		
Define-XML	SDTM : ADaM :	
Controlled Terminology	SDTM : ADaM :	
MedDRA		
WHODrug Global		
(Others)		(Purpose of use)

ADRG

1.3 Study Data Standards and Dictionary Inventory

Standard or Dictionary	Versions Used
SDTM	
SDTM Controlled Terminology	
ADaM	
ADaM Controlled Terminology	
Data Definitions	
TAUG (if applicable)	

Form A 4.1.1b - SDTM(1/2)

cSDRG

2.3 Trial Design Datasets

Are Trial Design datasets included in the submissi

(If no, delete the remainder of this section. If ye
2.3 and provide additional information below.)

2.3.1 TA – Trial Arms

(Text here)

2.3.2 TE – Trial Elements

(Text here)

2.3.3 TV – Trial Visits

(Text here)

2.3.4 TI – Trial Inclusion/Exclusion Criter

(If criteria are not fully described in TI, complete A
hyperlink to the pages in blankcrf.pdf that contain t

2.3.5 TS – Trial Summary

(Text here)

Form A

The datasets planned to be submitted (SDTM)	
Definition file	☐ define.xml
Review's guide	☐ Study Data Reviewer's Guide
Dataset	Submission *Check for domains to be submitted. Do nc are not be submitted.
TA	☐
TD	☐
TE	☐
TI	☐
TS	☐
TV	☐

define.xml is required to be submitted, so there is no need to mention that it is submitted in cSDRG.

cSDRG is required to be submitted, so there is no need to mention that it is submitted in cSDRG.

Form A 4.1.1b - SDTM(2/2)

cSDRG

3.4 SDTM Subject Domains

Dataset – Dataset Label	Efficacy	Safety	Other	Custom	SUPP-	Related Using RELREC
AE – Adverse Events		X				
DM – Demographics			X			
DS – Disposition			X			
EX – Exposure			X			

3.4.x Dataset – Dataset Label

If a custom domain is being created, it should be listed in 3.4.x.

3.3 Annotated CRFs

(Text here or indicate this section is not applicable)

Form A

If Japanese data is not created, there is no need to prepare a column for Japanese data creation in the cSDRG.

Dataset	Check the domains which will be submitted. The domains which are not officially adopted in the standard version should be described in the "Custom domains" field.	Check the corresponding one			Notes
		SUPP	Include data in Japanese	SUPP Include data in Japanese	
AE	☐	☐	☐	☐	
CE	☐	☐	☐	☐	
VS	☐	☐	☐	☐	
Custom domains					
	☐	☐	☐	☐	
	☐	☐	☐	☐	
	☐	☐	☐	☐	
Annotated CRF	☐ Annotated CRF will be submitted				

Form A 4.1.1b - ADaM(1/2)

define.xml is required to be submitted, so there is no need to mention that it is submitted in ADRG.

ADRG is required to be submitted, so there is no need to mention that it is submitted in ADRG.

Form A

The dataset planned to be submitted as electronic data (ADaM) *Describe the dataset name and the contents in the column.	
Definition file	☐ define.xml Submission of Analysis Results Metadata ☐ Submitted ☐ Included in define.xml ☐ Other ( ) ☐ Not submitted
Review's guide	☐ Analysis Data Reviewer's Guide

ADRG

7. Submission of Programs

All programs for analysis datasets and primary and secondar
all created on a <text here> platform using <version>. The i
ADaM datasets is <date>.

7.1 ADaM Programs

Program Name	Output	Macro Used

7.2 Analysis Output Programs

Program Name	Output Number	Title

Form A 4.1.1b - ADaM(2/2)

Form A

Dataset	Contents of the dataset	Include data in Japanese (If applicable, please check)
		☐
		☐
		☐

Submission of programs for creating ADaM
- ☐ All the programs will be submitted
- ☐ Only some programs will be submitted
- ☐ Not submitted (The reason:)

If Japanese data is not created, there is no need to prepare a column for Japanese data creation in the ADRG.

ADRG

7.1 ADaM Programs

Program Name	Output	Macro Used

5.2 Analysis Datasets

Dataset Dataset Label	Class	Efficacy	Safety	Baseline or other subject characteristics	PK/PD	Primary Objective	Structure
ADSL Subject Level Analysis Dataset	ADSL			X			One observation per

5.2.1 ADSL – Subject Level Analysis Dataset

(insert your text here)

Form A 4.1.1b - Other Datasets

cSDRG

3.2 Traceability Flow Diagram

(Diagram here, or indicate the diagram is located in th
Appendix.)

Form A

The dataset planned to be submitted as electronic data (Other)	
File name (include extensions)	Contents

ADRG

1.4 Source Data Used for Analysis Dataset Creation

(insert your text here)

Include the following text if applicable: Please refer to the Legacy D
Appendix for additional details.

5.2.x Dataset – Dataset Label

(A new section is required for each dataset that is hyperlink
be copied to create a new section for each dataset. The text
match the dataset name and label.

"Other datasets" includes population/record flag data, Adverse Events of Special Interests (AESI), or any additional data that provides traceability flow, that are NOT in ADaM format and would be stored in *misc* folder. These data may be mentioned in the following sections:

- Population flag/record flag data: ADRG 1.4
- AESI: ADRG 5.2.x
- Additional data that provides traceability flow: cSDRG 3.2

Form A 4.1.1c - Validation Engine

Form A

Validation tool and version (Describe each version if versions are different between SDTM and ADaM)	

cSDRG

4.1 Conformance Inputs

Was a validator used to evaluate conformance? <Yes> <No>

If yes, specify the version(s) of the validation rules:

(Text here)

Were sponsor-defined validation rules used to evaluate conformance? <Yes> <No>

If yes, describe any significant sponsor-defined validation rules:

(Text or table here. If significant amount, include as an appedix)

Were the SDTM datasets evaluated in relation to define.xml? <Yes> <No>

Was define.xml evaluated? <Yes> <No>

ADRG

6.1 Conformance Inputs

Specify the software name and version for the analysis datasets

(Text here)

Specify the version of the validation rules (i.e. CDISC, FDA) for the analysis datasets

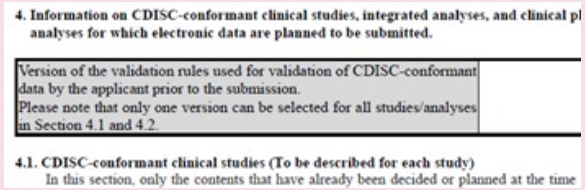
(Text here)

Specify the software name and version for the define.xml

Form A 4.1.1.c – Validation Engine (Notes)

Input the validation rules version specified by PMDA (Ver.2.0 or Ver.3.0, as of November 2022).
See PMDA's website for details.

Form A Section 4



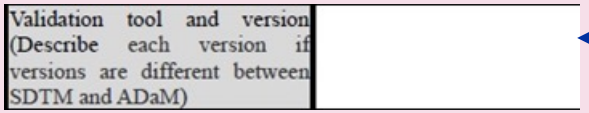
4. Information on CDISC-conformant clinical studies, integrated analyses, and clinical pl
analyses for which electronic data are planned to be submitted.

Version of the validation rules used for validation of CDISC-conformant data by the applicant prior to the submission. Please note that only one version can be selected for all studies/analyses in Section 4.1 and 4.2.	

4.1. CDISC-conformant clinical studies (To be described for each study)
In this section, only the contents that have already been decided or planned at the time

e.g.)
PMDA Study Data Validation Rules Ver.3.0

Form A Section 4.1.1c



Validation tool and version (Describe each version if versions are different between SDTM and ADaM)	

Input the tool version used for validation.

e.g.)
Pinnacle version and Engine are listed(e.g. “Pinnacle 21 Enterprise v4.2.0 and Engine is PMDA(2010.2)”).

Form A 4.1.1c - Issue Summary

Form A

SDTM	
Explanation about conformance - Describe the CDISC (SDTM) conformance	
Dataset	Contents (including Rule ID)
ADaM	
Explanation about conformance - Describe the CDISC (ADaM) conformance	
Dataset	Contents (including Rule ID)

Be careful not to forget to include the **Rule ID** in the cSDRG/ADRG document.

cSDRG

4.2 Issues Summary

(text here and/or use following table)

Dataset	Diagnostic Message	Severity	Count	Explanation

ADRG

6.2 Issues Summary

(insert your text here and/or use following table)

Dataset	Diagnostic Message	Severity	Count	Explanation

Form A 4.1.1d – Analysis Information

Form A

d. Analysis information
Submission of analysis programs ☐ Submitted with macro code ☐ Since the macro code are not submitted, specifications that show the ar (The reason why the macro code cannot be submitted:) ☐ Since the analysis programs are not submitted, specifications that show th (The reason why the analysis programs cannot be submitted: If the contents are included in other materials, the name of those mate
Software used for the analyses In case more than one software used, describe all the names of software. Software name (version) : Analysis environment (operating system, version, etc.):

ADRG

7. Submission of Programs

All programs for analysis datasets and primary and secondary
all created on a <text here> platform using <version>. The int
ADaM datasets is <date>.

7.1 ADaM Programs

Program Name	Output	Macro Used

7.2 Analysis Output Programs

Program Name	Output Number	Title

7.3 Macro Programs

Program Name	Purpose

Summary

- Technical Conformance Guide was last updated on April 1st 2022 and the existing Form A covered all items mentioned therein.
- Reviewer's guides can now be referenced when filling out Form A.
- PHUSE assessed where each items on Form A can be included in the reviewer's guides.

"Technical Conformance Guide" = PMDA Technical Conformance Guide on Electronic Study Data Submissions (dated April 1, 2022)

Thank you

- **<u>Working Group Members</u>**
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  - Rie Kageyama *Sumitomo Pharma*
  - Yasuhiko Ozawa *AstraZeneca*
  - Ryo Watanabe *A2 Healthcare Corporation*
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Agenda

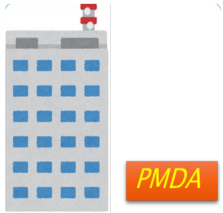
- Looking back in 2022
- Form A and Reviewer's Guide
- Issue Summary Writing Guide

Theme2 : Issue Summary Writing Guide

- **Background**
  - Last year, PHUSE Japan e-data submission task team and CJUG SDTM/ADaM have collected the Issue Summary explanations which were shared at PMDA Consultation meeting. This year's task is the next step of this.

Form A

Dataset	Diagnostic Message	Severity	Count	Explanation
LB	Missing Units on Value	Error	22	**Not an error:** Lab results for pH and Specific Gravity have no units



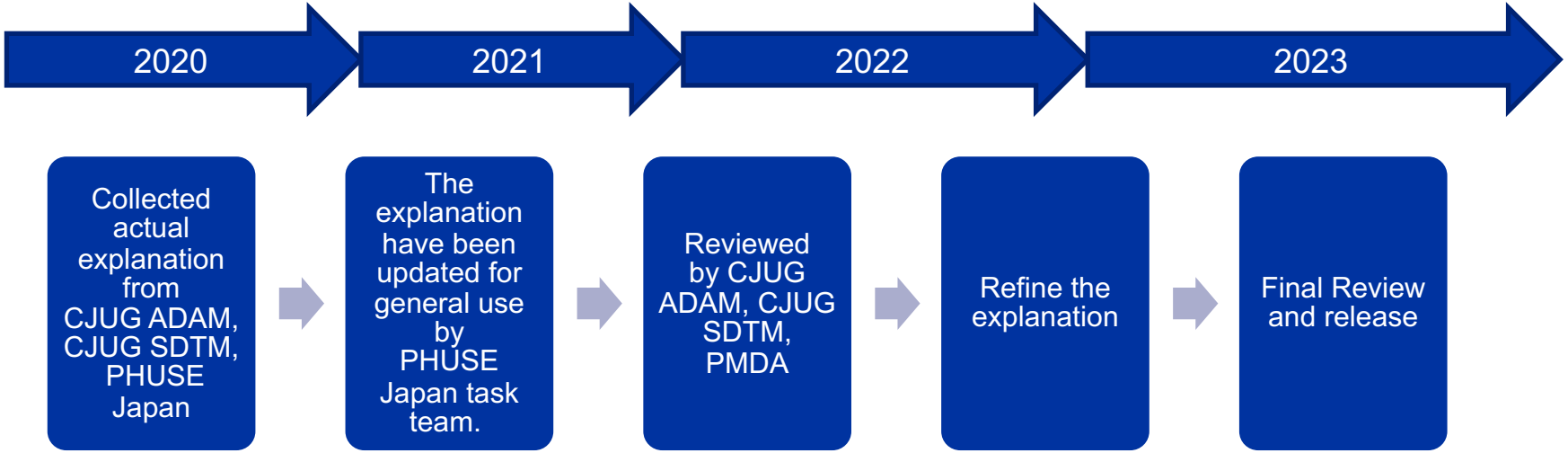
Theme2 : Issue Summary Writing Guide

How can we create user-friendly guidance?

- When does the error occurs?
- How can we explain the Error due to Legacy data conversion?
- The material to be used with the Global Team

Theme2 : Issue Summary Writing Guide

- **Goal**
  - Make it easy for everyone to write Issue summary section in SDRG and ADRG
- **Objective**
  - Create the guidance/metadata of explanation with simple and clear explanation
  - Improve the quality of the explanation


2020
2021
2022
2023
Collected actual explanation from CJUG ADAM, CJUG SDTM, PHUSE Japan
The explanation have been updated for general use by PHUSE Japan task team.
Reviewed by CJUG ADAM, CJUG SDTM, PMDA
Refine the explanation
Final Review and release

Theme2 : Issue Summary Writing Guide

RULE ID	PMDA Severity	Description\Explanation
CT2001	Error	As per sponsor's data collection CRF standard at the time of this study start in 2011, this response was collected as 'NONE' on the CRF and was mapped to AEACN='NONE'. Since the CSR for this study is final and CSR listing displays the value of 'NONE' as collected on the CRF, sponsor determined to keep value as 'NONE' instead of remapping it to 'DOSE NOT CHANGED' to ensure traceability back from the finalized CSR to SDTM data.
CT2003	Error	The LBTESTCD values were mapped as per sponsor's data collection standard at the time of this start in 2011. The CSR for this study is final and many tables and listings in the CSR are generated using these collected values of LBTESTCD. Remapping of these collected LBTESTCD values to CDISC CT will cause loss of traceability back from finalized CSR to SDTM data. Therefore, sponsor has determined to keep the values as collected. Please see
SD0003	Error	Subject XXX, AEDECOD='YYYY' did not report were queried and the site confirmed no addition AEENDTC=2015-10T05:00, but should be 2015
SD0036	Error	Missing value for PPSTRESC, when PPORRES →The variable PPORRES, in terms of traceabili the output of WinNonlin. For parameter where P

RULE ID	PMDA Severity	Description\Explanation
DD0013	Error	Duplicate Method OID / Content is correct. Message refers to STUDYID and USUBJID. These variables have multiple Origins ('Predecessor' in ADIS, 'Derived' in the others) assigned in multiple datasets. However, the correct origin is 'Predecessor'.
DD0032	Error	MO Domain description has assigned as per SDTM guideline 3.2. MO domain abbreviation value is not present under 'DOMAIN' extensible codelist therefore this flagged in pinnacle report.
DD0033	Error	For CodedValue="ng/mL": NCICode=C85494 and Code=C67306. Maybe pinnacle system issue, this NCI code can be found in official codelist file.
DD0039	Error	This is a false positive error. DD0039and other rules (e.g., DD0059,DD0060) not directly related to Define-XML standard are removed in newupcoming Community release 3.0.0.Define.xml file should describestructure and content of actual studydata rather than be responsible forcorrect implementation of SDTMstandard.

Deliverable

RULE ID	DOMAINS	PMDA Severity	エラー概要	Example Sentences	NOTES
SD0036	FINDINGS	Error	--ORRESに値があるけれど、--STRESCが欠損	1.何らかの理由で換算できなかった場合 *理由/背景の説明*のため、*--STRESC*の値を求めることができなかったことにより欠測値であるが、*理由/背景の説明*のため、問題ないと判断した。 2.XXORRESが0でXXSTRESCが欠測の場合 *理由/背景の説明*のため、*--STRESC*が欠測値であるが、*理由/背景の説明*のため、問題ないと判断した。	1.何らかの理由で換算できなかった場合 '換算係数がない、単位がない、等変換できない理由を記載する '2.XXORRESが0でXXSTRESCが欠測の場合 PPORRESが0でPPSTRESCが欠測等のケース

Build Standard explanation

- **Use Standard explanation**

  Created by phuse CJUG ADaM Team

  Consulted with Pmda

Future

Present

- To struggle to consider the explanation
- Explanation varies from company to company

Deliverable

- Japanese version and English version are available

Example Sentences
1.何らかの理由で換算できなかった場合 *理由/背景の説明*のため、*--STRESC*の値を求めることができなかったことにより欠測値であるが、*理由/背景の説明*のため、問題ないと判断した。 2.XXORRESが0でXXSTRESCが欠測の場合 *理由/背景の説明*のため、*--STRESC*が欠測値であるが、*理由/背景の説明*のため、問題ないと判断した。

Example Sentences
1.When it is unable to convert for any reason This is a missing value because the value of *--STRESC* could not be obtained because of *the explanation of (reason/background(*, but it is acceptable because of *the explanation of (reason/background).* 2.When XXORRES is 0 and XXSTRESC is missing Due to *(reason/background) --STRESC* is missing value, but it is acceptable because *(reason/background)*.

Example

Rule ID Message	SD0035 : Missing value for --DOSU, when --DOSE, --DOSTXT or --DOSTOT is provided
Description	Dose Units (--DOSU) must be populated, when Dose per Administration (--DOSE), Dose Description (--DOSTXT) or Total Daily Dose (--DOSTOT) is provided.
主な理由	✓ 単位がない項目 ✓ CRFで単位を収集していない ✓ 単位はECDOSTXT(Dose Description)に入れている

Example

RULE ID	DOMAINS	PMDA Severity	エラー概要	Example Sentences	NOTES
SD0035	INTERVENTIONS	Error	投与量 'Dose per Administration (--DOSE)or Dose Description (--DOSTXT) or Total Daily Dose (--DOSTOT)が格納されているが、'Dose Units (--DOSU)単位 が格納されていない。	CRF設計上、*XXDOSU*で適切な単位がCRF上選択できないため、*XXDOSU*は欠測値であるが、その場合は*XXDOSTXT*に記載している。	各社のCRF設定に依存する。各Studyのデータ内容とCRF仕様を確認の上、説明を記載する。 ※例示は記載例の1例であり、各Studyの状況に合わせてエラーの理由、記載内容はご検討ください。
				<XXDOSU> is a missing value because the appropriate unit for <XXDOSU> <cannot be selected|not available> on the CRF due to study design. In that case it is recorded in <XXDOSTXT>.	Depending on the company's CRF design. Please confirm the study CRF design and describe the reason for each study. *The example sentences is just an example of description. Please consider the reason for error and the description according to the situation of each study.

Example

Rule ID Message	SD1206 ： EXSTDTC date is after RFXENDTC SD1207 ： EXENDTC date is after RFXENDTC
Description	Start Date/Time of Treatment (EXSTDTC) variable value must be less than or equal to Date/Time of Last Study Treatment (RFXENDTC). End Date/Time of Treatment (EXENDTC) variable value must be less than or equal to Date/Time of Last Study Treatment (RFXENDTC).
主な理由	✓ 最終投与日(EXSTDTC or EXENDTC)がEXDOSE=0である (休薬を除いた最終投与日の日付をRFXENDTCに格納しているケース)

Example

RULE ID	DOMAINS	PMDA Severity	エラー概要	Example Sentences	NOTES
SD1206	EX	Error	投与開始日は終了日と同じかそれ以前の日付でないといけない	Date/Time of Last Study Treatment (RFXENDTC)は、治験薬の最終暴露日としているが、*理由/背景の説明*のため、EXSTDTCがRFXENDTCより遅い日付となった。	注釈： 上記理由の可能性が高いが、CRF designによっては異なる可能性もあるので、Study毎に確認してください。
SD1207	EX	Error	(投与終了日)EXENDTCが(試験終了日)RFXENDTCの後	RFXENDTCは投与量が0のレコードを除いて算出しているため	※例示は記載例の1例であり、各Studyの状況に合わせてエラーの理由、記載内容はご検討ください。 SD1206も合わせて参考にしてください。

Date/Time of Last Study Treatment (RFXENDTC) is defined as the date of the final exposure to investigational product; however, because *reason/background*, EXSTDTC was later than RFXENDTC.	The Example Sentence is most likely the reason for the Error, but, they may differ depending on the CRF design, so please check them for each study.
Because RFXENDTC was derived excluding records of dose =0, EXENDTC date is after RFXENDTC.	*This is an Example of description, Please consider the reason for error and the description according to the situation of each study. Please also refer to EX 1206.

Example

Rule ID Message	SD1212 : --STRESN does not equal –STRESC
Description	Standardized Result in Numeric Format (--STRESN) variable value should be equal Standardized Result in Character Format (--STRESC) variable value, when Standardized Result in Character Format (--STRESC) variable value represents a numeric value.
主な理由	✓ 丸め誤差 1.--STRESCには、丸めた値を格納しているため 2.XPTのフォーマットに起因するエラー

LBSTRESC	LBSTRESN
60.0	60.0
MODERATE	
12.1	12.1
TRACE	
1+	
BLQ	
33.8	33.8

Example

RULE ID	DOMAINS	PMDA Severity	エラー概要	Example Sentences	NOTES
SD1212	FINDINGS	Error	Standardized Result in Numeric Format (--STRESN) variableが Standardized Result in Character Format (--STRESC) variable valueと同じ値ではない	*XXSTRESN* と*XXSTRESC* は同じ値であるが、*理由/背景の説明（丸めや有効桁数によるなど）*のため検出された。*理由/背景の説明*のため、問題ないと判断した。	※例示は記載例の1例であり、各Studyの状況に合わせてエラーの理由、記載内容はご検討ください。

Example Sentences	NOTES
<XXSTRESN> and *<XXSTRESC>* have the same value but are detected as different due to *[<the reason/background> (e.g. due to rounding or number of significant digits)]*. This was not updated.	*This is an Example of description, Please consider the reason for error and the description according to the situation of each study.

How to use

Here is the description of this file. Read this sheet first.
There are 3 sheets: SDTM Rules, ADaM Rules, and Define-XML Rules.
Each sheet has 2 columns ,"Example Sentences" and "NOTES".

Example Sentences	NOTES
1.When a code other than the codelist of SDTM CT is used The following variables are variables for which the extension code cannot be used, but were set to XXXX "for the reason of XXXX. The corresponding code is still used in the CSR (reason/background clarification). ・APPROVED TO CONTINUE ・ACKNOWLEDGED, NO ACTION TAKEN. SUBJECT PARTICIPATION COMPLETED ・PARTICIPATION TERMINATED 2.If this is a Pinnacle bug	Reject/Error varies depending on the variable If it is an error, it may be avoided by explanation, but if it is a rejection, it must be corrected. See page 31 for the link below. <https://www.pinnacle21.com/sites/default/files/blog/2019/12/pmda-new-validation-rules-jp.pdf> If a list of non-extensible codes used in SDRG Section 3.3 .X is prepared, it is acceptable to refer to the relevant part.

README | SDTM Rules | ADaM Rules | Define-XML Rules

Prerequisites - to use properly

- ✓ Please review errors carefully.
- ✓ You are responsible for all contents in the explanation.

- **Schedule**
  - 2022 : Proofread
  - 2023 : Release in PHUSE Advance Hub

Stay Tuned…

Coming Soon!

Thank you

- **Task Members**
  - Kayo Inushima — *Biogen Japan, Ltd.*
  - Noriyuki Shibayama — *Janssen Pharmaceutical K.K.*
  - Zhengyan Luo — *Bristol-Myers Squibb K.K.*
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