



IS04: An Introduction to SDTM – 298 pages in 20 minutes?!

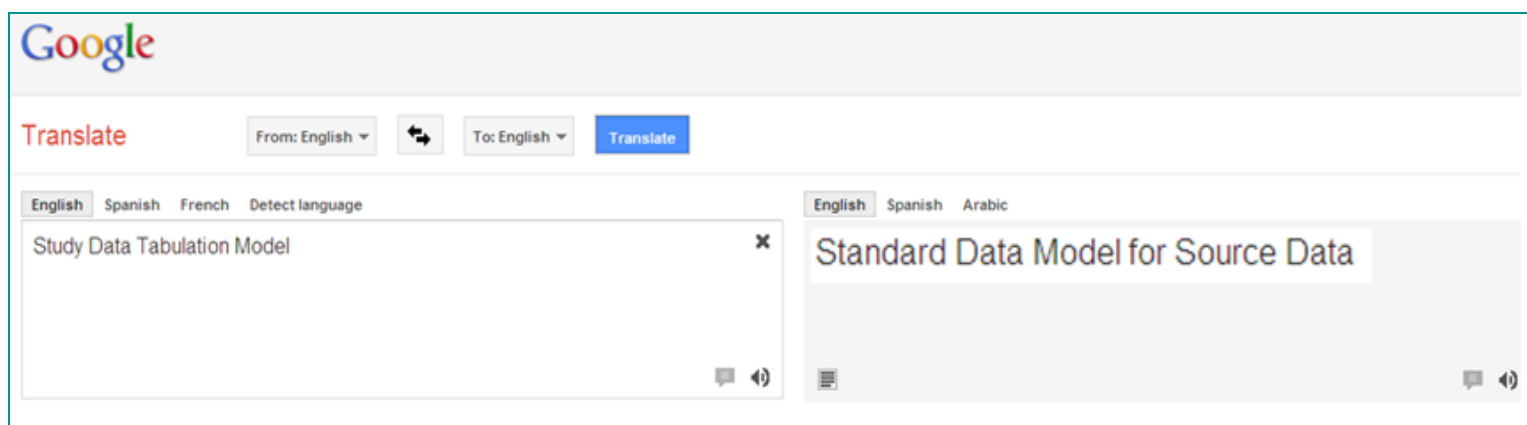
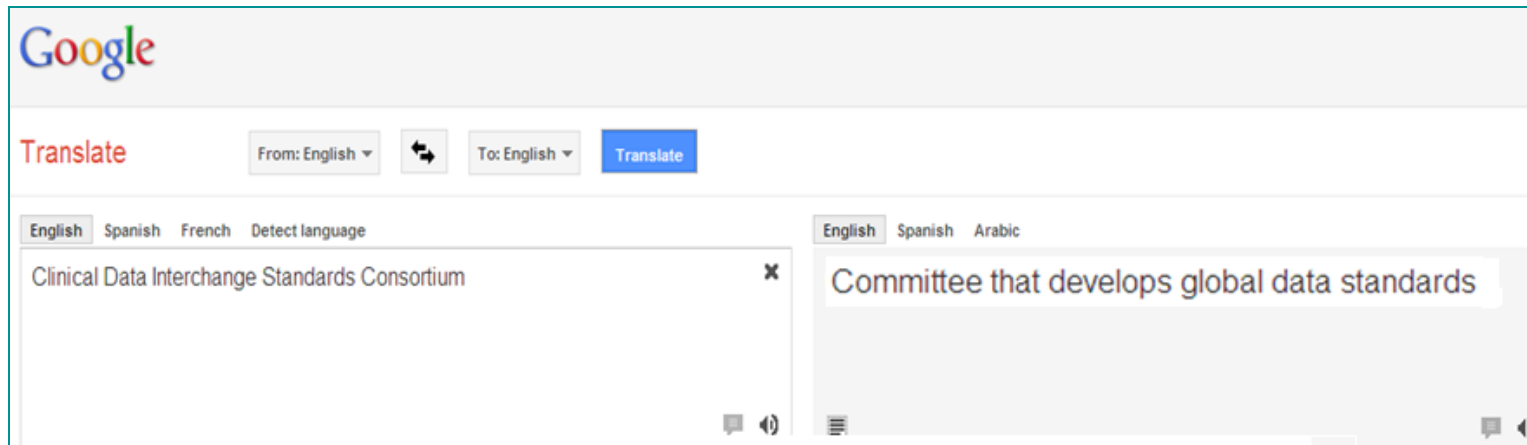
Jennie Mc Guirk



- Introduction
- SDTM Framework
- SDTM Implementation and Examples
- SDTM Compliance
- Summary

Who are CDISC? What is SDTM?

<http://www.cdisc.org/>



Study Data Tabulation Model

SDTM Implementation Guide

Dataset



Data Class

Obs	Y	Z	C
1	1	8	A
2	0	7	A
3	3	6	A
4	2	5	B
5	0	6	B
6	3	.	B

Variable Role

SDTM Framework: General Observation Class



Interventions

Treatments that are administered to the subject

Conmeds (CM)

Exposure (EX)



Events

Planned protocol milestones, occurrences, conditions, or incidents

Adverse Events (AE)

Disposition Events (DS)



Findings

Observations resulting from planned evaluations

Vital Signs (VS)

Physical Exam (PE)

SDTM Fundamentals: Other Data Classes



Special Purpose

**Demographics
(DM)**

Comments (CO)

Subject Visits (SV)

**Subject Elements
(SE)**



Relationship

**Related Records
(RELREC)**

**Supplemental
Qualifiers
(SUPP--)**



Trial Design

Trial Summary (TS)

Trial Arms (TA)

Trial Inclusion (TI)

**Trial Visits (TV)
Trial Elements (TE)**

SDTM Framework: Variable Roles



Identifier

Variables used to identify the record

Study Identifier
(STUDYID)

Subject Identifier
(USUBJID)

Sequence Identifier (--SEQ)



Topic

Specifies the focus of the observation

Lab Test Name
(LBTEST)

Adverse Event Term
(AETERM)

Reported Drug Name (CMTRT)



Timing

Timing of the observation

Lab Assessment Date (LBDTC)

Adverse Event Start Date
(AESTDTC)

Exposure End date (EXENDTC)



Qualifier

Values that describe the results or traits of the observation

Lab Test Result (LBORRES)

Adverse Event Severity
(AESEV)

Conmed Dose (CMDOSE)

SDTM Framework: Core Variables



Required

Basic to the
identification of
a data record

Must always be
present

Cannot be null



Expected

Establish the
observation
context

Must always be
present

Can be null



Permissible

Present if
collected or
derived

Must be present
if collected

Can be null or
excluded

Data Class

General Observation

Special Purpose

Relationship

Trail Design

Variable Role

Identifier

Topic

Timing

Qualifier

Core Variables

Required

Expected

Permissible

SDTM Implementation

Creating a Mapping

1.
Determine
the **Data**
Class

2. Identify
Required
Variables

3. Identify
Expected
Variables

4. Identify
applicable
Permissible
Variables

5. Identify
Relationship
Variables

SDTM Implementation Example 1

No relationship variables

No expected variables

6.1.1 CONCOMITANT MEDICATIONS — CM

cm.xpt, Concomitant Medications — Interventions, Version 3.1.2., One record per recorded intervention occurrence or co-

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	References
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req	SDTM 2.2.4
DOMAIN	Domain Abbreviation	Char	CM	Identifier	Two-character abbreviation for the domain.	Req	SDTM 2.2.4 , SDTMIG 4.1.2.2 , SDTMIG Appendix C2
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req	SDTM 2.2.4 , SDTMIG 4.1.2.3
CMSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req	SDTM 2.2.4
CMGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm	SDTM 2.2.4 SDTMIG 4.1.2.6
CMSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Examples: a number pre-printed on the CRF or record identifier defined in the sponsor's sample: line number on a concomitant medication page	Perm	SDTM 2.2.4
CMTRT	Reported Name of Drug, Med, or Therapy	Char	CMDOSE	Topic	Verbatim medication name that is collected		SDTM 2.2.1
CMROUTE				Route			
CMMODIFY	Modified Reported Name	Char	CMDOSE	Qualifier	Contains a reference to the text that contains the modified text.	Perm	SDTM 2.2.1 , SDTMIG 4.1.3.6
CMDECOD	Standardized Medication Name	Char	*	Synonym	Standardized or dictionary-derived text description of the drug, or WHO Drug Name. Equivalent to the generic medication name.	Perm	SDTM 2.2.1 , SDTMIG 4.1.3.6

5. Identify Relationship Variables



SDTM Implementation Example 2

No relationship variables

Events

Clinical Research

AESEV	Severity/Intensity	Char	(AESEV)	Record Qualifier	The severity or intensity of the event. Examples: MILD, MODERATE, SEVERE.	Perm	SDTM 2.2.2
AESER	AESER	Char	(NY)	Record Qualifier	Is this a serious event?	Exp	SDTM 2.2.2
AEACN	AEACN	Char	(ACN)	Record Qualifier	Describes changes to the study treatment as a result of the event. AEACN is specifically for the relationship to study treatment. AEACNOTH is for actions unrelated to dose adjustments of study treatment. Examples of AEACN values include ICH E2B values: DRUG WITHDRAWN, DOSE REDUCED, DOSE INCREASED, DOSE NOT CHANGED, UNKNOWN or NOT APPLICABLE	Exp	SDTM 2.2.2
AEACNOTH	Other Action Taken	Char		Record Qualifier	Describes other actions taken as a result of the event that are unrelated to dose adjustments of study treatment. Usually reported as first text.	Perm	SDTM 2.2.2
AEREL	AEREL	Char	*	Record Qualifier	Records the investigator's opinion as to the causality of the event with the treatment. ICH E2A and E2B examples include NOT RELATED, UNLIKELY RELATED, POSSIBLY RELATED, RELATED. Controlled Terminology may be defined in the future. Check with regulatory authority for population of this variable	Exp	SDTM 2.2.2
AESTDTC	AESTDTC	Char	ISO 8601	Timing		Exp	SDTM 2.2.5, SDTMIG 4.1.4.1, 4.1.4.2
AEENDTC	AEENDTC						SDTM 2.2.5, SDTMIG 4.1.4.1, 4.1.4.2
AEPRESP	Pre-Spec Event						7

5. Identify Relationship Variables



SDTM Implementation Example 3

LBCAT	LBCAT	Test	Char	*	Grouping Qualifier	Used to define a category of related records across subjects. Examples: such as HEMATOLOGY, URINALYSIS, CHEMISTRY.	Exp	SDTM 2.2.3, SDTMIG 4.1.2.6
LBORRES	LBORRES		Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp	SDTM 2.2.3, SDTMIG 4.1.5.1
LBORRESU	LBORRESU		Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for LBORRES. Example: g/L.	Exp	SDTM 2.2.3, SDTMIG 4.1.3.2, SDTMIG 4.1.5.1
LBORNRL0	LBORNRL0	Reference Range Lower Limit in Orig Unit	Char		Variable Qualifier	Lower end of reference range for continuous measurements in original units. Should be populated only for continuous results.	Exp	SDTM 2.2.3
LBORNRI	LBORNRI	Reference Range Upper Limit in Orig Unit	Char		Variable Qualifier	Upper end of reference range for continuous measurements in original units. Should be populated only for continuous results.	Exp	SDTM 2.2.3
LBSTRESC	LBSTRESC	Character Result/Finding in Std Format			Result Qualifier	Contains the result value for all findings, copied or derived from LBORRES in a standard format or standard units. LBSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in LBSTRESN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in LBORRES and these results effectively have the same meaning, they could be represented in standard format in LBSTRESC as "NEGATIVE". For other examples, see general assumptions.	Exp	SDTM 2.2.3, SDTMIG 4.1.5.1
LBSTRESN	LBSTRESN	Standardized Result/Finding			Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from LBSTRESC. LBSTRESN should store all numeric test results or findings.	Exp	SDTM 2.2.3, SDTMIG 4.1.5.1
LBSTRESU	LBSTRESU	Standardized Unit		(UNIT)	Variable Qualifier	Standardized unit used for LBSTRESC or LBSTRESN.	Exp	SDTM 2.2.3, SDTMIG 4.1.3.2, SDTMIG 4.1.5.1
LBSTNRLO	LBSTNRLO	Reference Range Lower Limit-Std Units			Variable Qualifier	Lower end of reference range for continuous measurements in standardized units. Should be populated only for continuous results.	Exp	SDTM 2.2.3
LBSTNRHI	LBSTNRHI	Reference Range Upper Limit-Std Units			Variable Qualifier	Upper end of reference range for continuous measurements in standardized units. Should be populated only for continuous results.	Exp	SDTM 2.2.3
LBNRIND	LBNRIND	Reference Range Indicator		*	Variable Qualifier	1. Indicates where the value falls with respect to reference range defined by LBORNRL0 and LBORNRI, LBSTNRLO and LBSTNRHI, or by LBSTNRC. Examples: NORMAL, ABNORMAL, HIGH, LOW. 2. Sponsors should specify in the study metadata (Commons column in the define.xml) whether LBNRIND refers to the ranges and results. 3. Should not be used to indicate clinical significance.	Exp	SDTM 2.2.3
LBBFL	LBBFL	Baseline						
VISITNUM	VISITNUM							
LBDMTC	LBDMTC	Date/Time						

5. Identify Relationship Variables



LBADD in SUPPLB
LBCLSIG = N in SUPPLB
LBCLSIG = Y in SUPPLB

SDTM Implementation

Linking SUPP to Parent

LB Family

Parent

Child

STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	VISIT	VISITNUM	LBORRE	LBADD	LBCLSIG
PROT123	LB	PROT123-001-001	1	ALB	ALBUMIN	CHEMISTRY	SCREENING	1	30	BUDAPEST	Y
PROT123	LB	PROT123-001-001	2	ALB	ALBUMIN	CHEMISTRY	WEEK 1	2	25	BUDAPEST	N
PROT123	LB	PROT123-001-001	3	ALB	ALBUMIN	CHEMISTRY	WEEK 2	3	21	BUDAPEST	N
PROT123	LB	PROT123-001-001	4	ALB	ALBUMIN	CHEMISTRY	END OF ST	4	17	BUDAPEST	N

Parent = LB

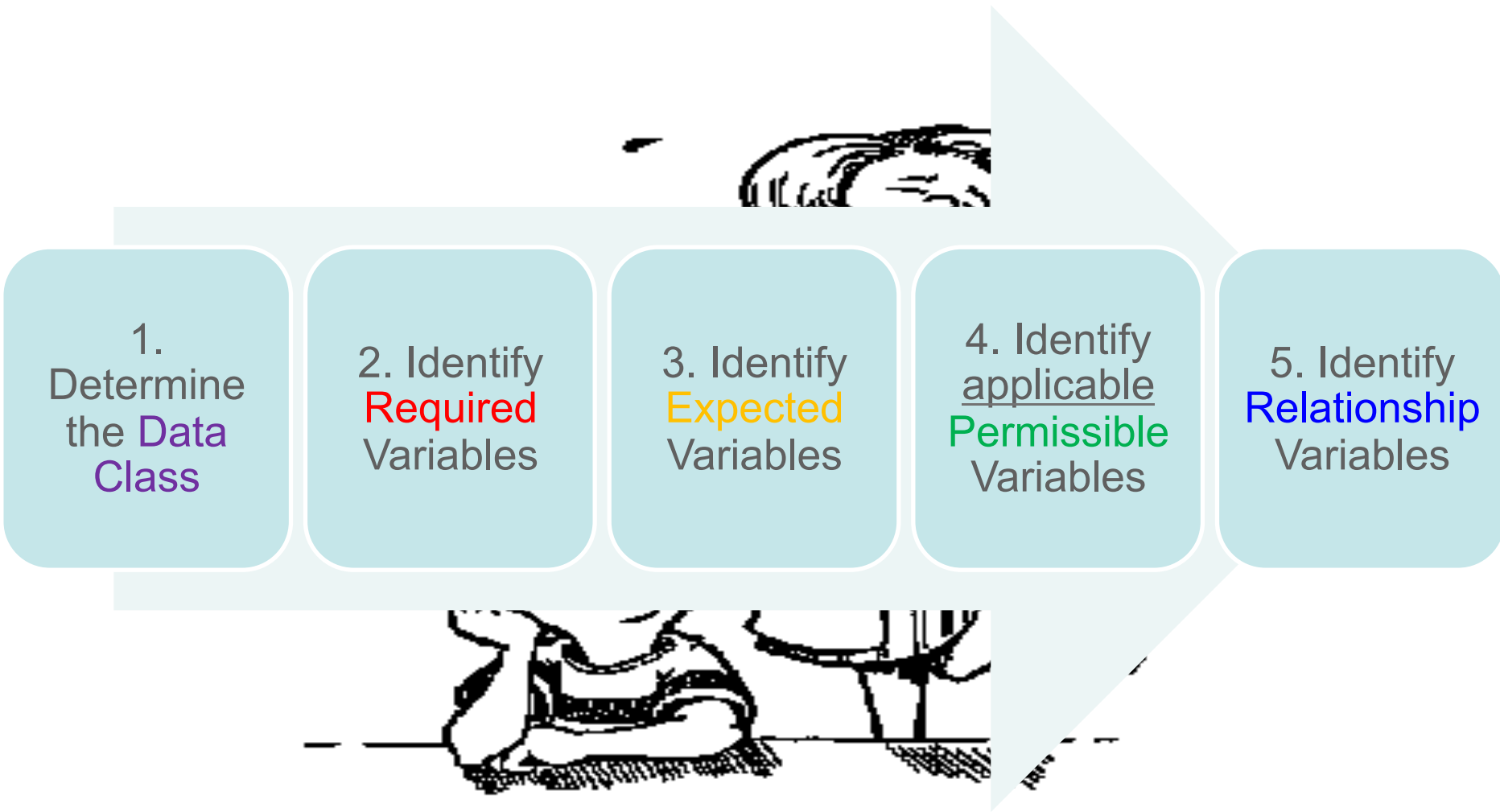
STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	VISIT	VISITNUM	LBORRES
PROT123	LB	PROT123-001-001	1	ALB	ALBUMIN	CHEMISTRY	SCREENING	1	30
PROT123	LB	PROT123-001-001	2	ALB	ALBUMIN	CHEMISTRY	WEEK 1	2	25
PROT123	LB	PROT123-001-001	3	ALB	ALBUMIN	CHEMISTRY	WEEK 2	3	21
PROT123	LB	PROT123-001-001	4	ALB	ALBUMIN	CHEMISTRY	END OF ST	4	17

Link via LBSEQ

STUDYID	RDOMAIN	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
PROT123	LB	LBSEQ	1	.LBADD	Lab Address	BUDAPEST	CRF	INVESTIGATOR
PROT123	LB	LBSEQ	2	.LBADD	Lab Address	BUDAPEST	CRF	INVESTIGATOR
PROT123	LB	LBSEQ	3	.LBADD	Lab Address	BUDAPEST	CRF	INVESTIGATOR
PROT123	LB	LBSEQ	4	.LBADD	Lab Address	BUDAPEST	CRF	INVESTIGATOR
PROT123	LB	LBSEQ	1	.LBCLS	Clin Sign	Y	CRF	INVESTIGATOR
PROT123	LB	LBSEQ	2	.LBCLS	Clin Sign	N	CRF	INVESTIGATOR
PROT123	LB	LBSEQ	3	.LBCLS	Clin Sign	N	CRF	INVESTIGATOR
PROT123	LB	LBSEQ	4	.LBCLS	Clin Sign	N	CRF	INVESTIGATOR

Child = SUPPLB

SDTM Implementation: Recap



1.
Determine
the **Data**
Class

2. Identify
Required
Variables

3. Identify
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Variables

4. Identify
applicable
Permissible
Variables

5. Identify
Relationship
Variables

SDTM Compliance – OpenCDISC

OpenCDISC Validator

File Help

What would you like to do? ☒ Validate Data ☐ Generate Define.xml

Standard:

Source Format:

Source Data:

You can select multiple files or folders as sources

Configuration:

Define.xml:

Optional

Report Format: [Report Settings](#)

Progress:

Waiting to begin.

Microsoft Excel - 2559008PK-020OpenCDISCreport21SEPT2012

File Edit View Insert Format Tools Data Window Help

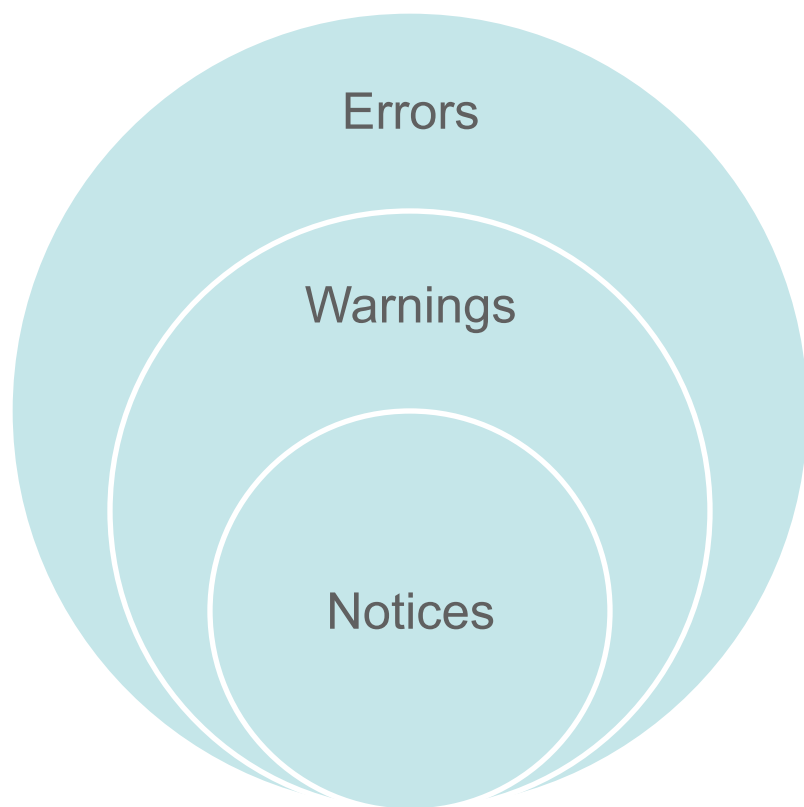
Type a question for help

OpenCDISC Validator Report

	A	B	C	D	E	F	G	H
1	OpenCDISC Validator Report							
2								
3	Configuration: S:\DIS\opencdisc-validator\1.3\opencdisc-validator\config\config-sdtm-3.1.2-amend-1.xml							
4	Define.xml: Not provided							
5	Generated: 2012-10-02T16:09:04							
6								
7	Processed Sources							
8	Name	Label	Class	Source	Records	Errors	Warnings	Notice
9	AE	Adverse Events	Events	AE.xpt	787	0	793	
10	Total				787	0	793	
11								
12	Unprocessed Sources							
13	Name	Label	Class	Reason		Errors	Warnings	Notice

Dataset Summary / Issue Summary / Details / Rules /

Ready



Consistency

Cross Reference

Format

Limit

Metadata

Presence

Data Quality

System

Terminology

SDTM Compliance – OpenCDISC

Cross Reference

And so on....

SD0064 Invalid subject

All Subjects (USUBSID) must be present in Demographics (DM) domain

Interventions,
Events, Findings, CO,
SE, SV

Cross-
reference

Error

SD0065

Invalid Subject Visit/Visit
Number

domain

~250 compliance checks in total

Cross-
reference

Warning

Format

The value of Sequence Number (--SEQ) variable must be unique for each record
within a subject

Interventions, Events,
Findings, CO, SE, SV, Consistency Error

SD0003 Invalid ISO 8601 value

Dates and times of day must conform to the ISO 8601 international standard

All

Format

Error

Presence

SD0001 No records in data source

'Domain table should have at least one record

All

Presence

Warning

SD0002

Null value in variable marked
as Required

Required variables (where Core attribute is 'Req') cannot be NULL for any records

All

Presence

Error

OpenCDISC

An Introduction to SDTM

298 pages in 20 minutes?!

Topics Covered

- The SDTM Framework
- 3 Basic Examples
- Linking SUPP-- Observations
- Compliance / OpenCDISC



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