



PhUSE Boston Single Day Event

OpenCDISC: Checks, Are They Useful, How to Interpret, Do All Need to be Fixed and How to Document

May 7th 2014

Majdoub Haloui

Principal Analyst, Statistical Submissions Management

Biogen idec

biogen idec

Disclaimer

Any views or opinions presented in this presentation are solely those of the author and do not necessarily represent those of Biogen Idec.

Topics

- OpenCDISC Validator Overview
- Checks, Are They Useful?
- Understanding the Validation Reports
- How to Interpret Errors/Warnings in these Reports?
- Do All Need to be Fixed, if not, how to Document?
- Conclusion

OpenCDISC Validator Overview (1)

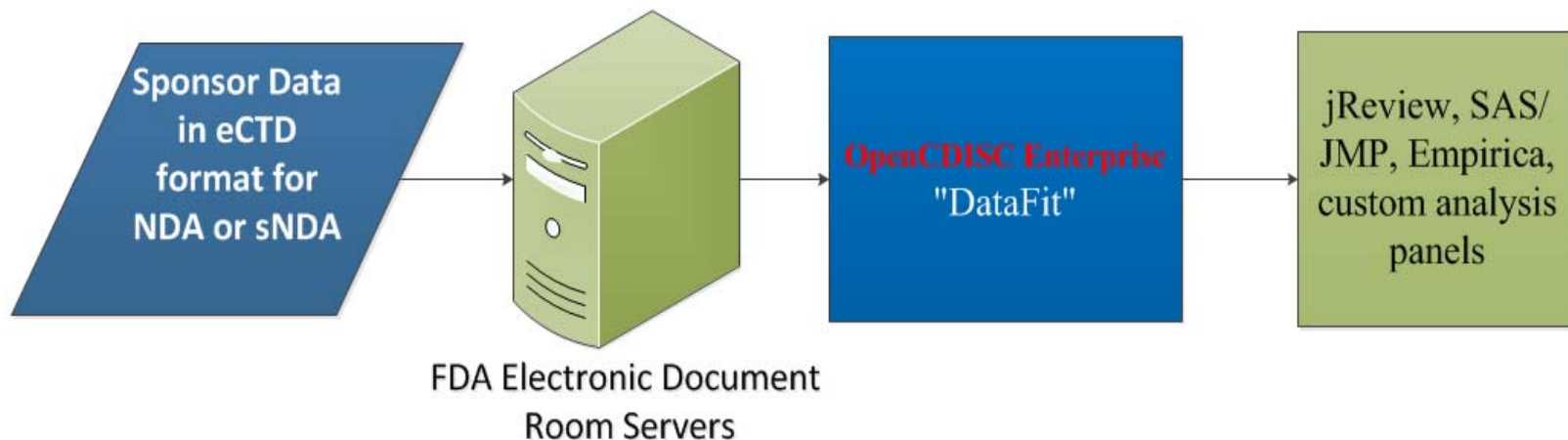
- Open Source application: Java and xml
- Free tool and easy to setup (<http://www.opencdisc.org/download>)
- Checks/validates SDTM, ADaM, SEND and Define.xml files
- Generates define.xml (limited)
- Options for different SDTM/ADaM versions:
 - SDTM 3.1.1 , 3.1.2, 3.1.3, 3.2
 - ADaM 1.0
 - SEND 3.0
- Options for define versions
 - 1.0 and 2.0
- OpenCDISC Validator Report (as Excel or CSV file)
- Fully configurable
- Latest version 1.5 (Support Define 2.0 and Dataset-xml format for a complete list of validation rule changes please refer to the [release notes](#).)

OpenCDISC Validator Overview (2)

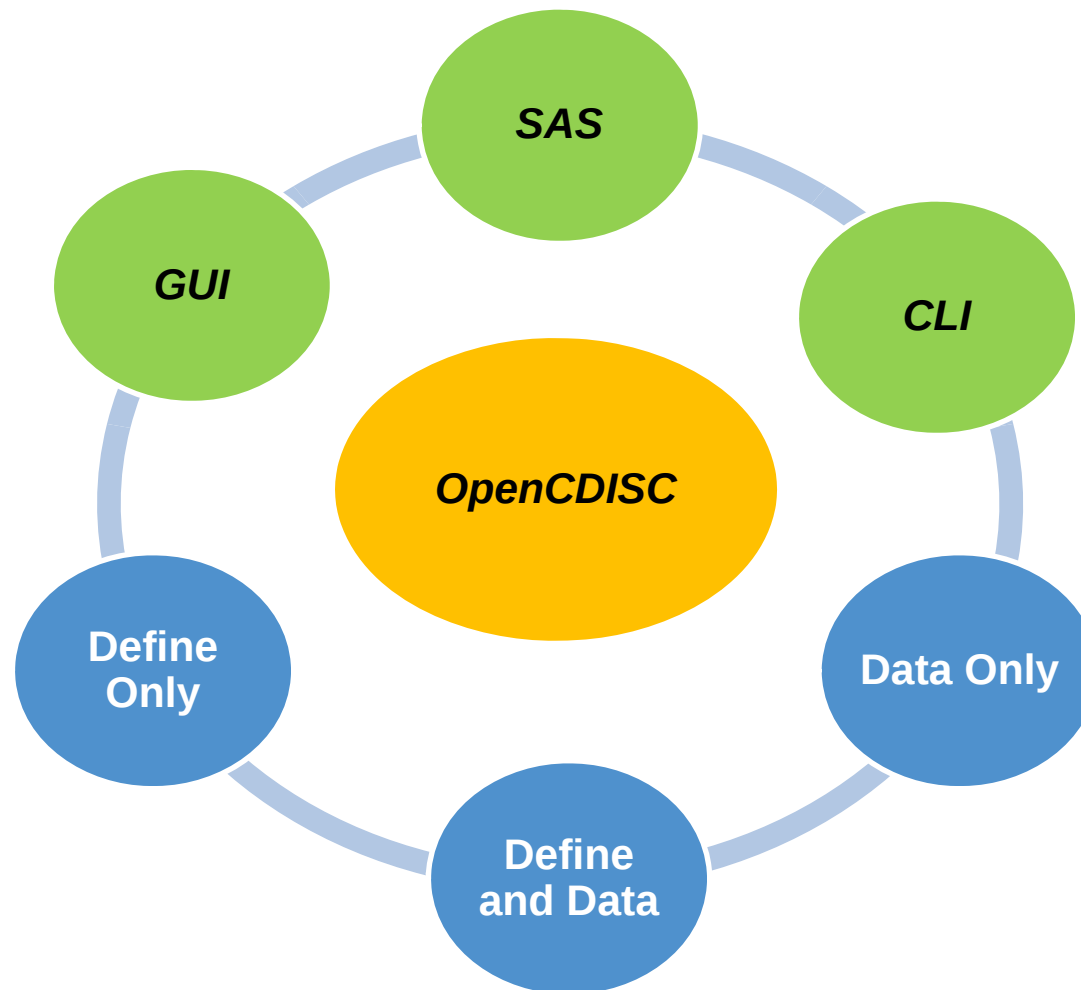
SOFTWARE FEATURES	VALIDATOR	ENTERPRISE	ON-DEMAND
Software license	Open Source	Subscription	Subscription
Metadata driven and configurable	✓	✓	✓
Reporting in Excel and CSV	✓	✓	✓
Enhanced reporting and scorecards		✓	✓
Manage issues throughout the study lifecycle		✓	✓
Communicate and collaborate with partners		✓	✓
Monitor data quality improvement over time		✓	✓
Track changes since last validation		✓	✓
Define.xml Designer		✓	✓
Customize specs for SDTM+ or sponsor formats		✓	
Customize rules per partner, project, or study		✓	
DEPLOYMENT OPTIONS			
Desktop Client	✓		
Dedicated Web Hosting		✓	
Multi-tenant Web Hosting			✓
Automated software and rule updates		✓	✓
Central configuration and management		✓	✓
Sandbox environment for training and testing		✓	
Increased scalability		✓	
QUALITY AND REGULATORY COMPLIANCE			
Benefits from testing by worldwide community	✓	✓	✓
Rigorous QA, performance, and scalability testing		✓	✓
GxP and 21 CFR Part 11 compliant		✓	✓
SUPPORT			
Community support forum	✓	✓	✓
Professional email and telephone support		✓	✓
Service level agreement		Customizable	Standard

Why Is OpenCDISC Validator Important?

- Currently used in the FDA submission checking process



Modes of Validation

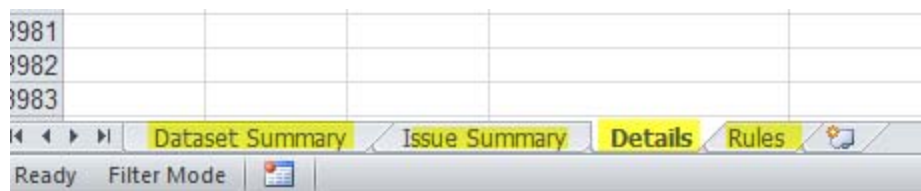


OpenCDISC Checks- Are They Useful?

- Yes, but depends on intended use
- Different users have different needs
 - Data Manager – data quality checks, data point level
 - Standards Group/Programmer – data integrity checks, issue level
 - Project manager – overall picture, rather than details on each issue or data point
- Different study life-cycle stages have different needs
 - Ongoing study – when some info is blinded, some standard checks are N/A
 - Companies sometimes use custom data standards (SDTM+, SDTM-like) and only convert to compliant SDTM before submission
- Be consistent with FDA and the rest of the industry
 - OpenCDISC Validator checks are an industry standard for
 - data standard compliance
 - regulatory requirements

OpenCDISC Validator Report (1)

- Validator Reports are based on predefined checks
- Different versions have a different set of checks/rules
- Four types of validation checks
 - CT Controlled Terminology
 - SD Study Data
 - DD Data Definition
 - OD Operation Data Model
- Each rule has an unique Rule ID, Message, Description, Category and Severity
- The Report contains four tabs or worksheets



OpenCDISC Validator Report (2)

Dataset Summary

- The Dataset summary tab provides information about each dataset in a quick, snapshot view

OpenCDISC Validator Report							
Configuration: C:\opencdisc-validator_1_5\config\config-sdtm-3.1.2.xml							
Define.xml: C:\work\updated_pilot_submission_package\Updated Pilot Submission Package\900172\m5\datasets\cdiscipilot01\tabulations\sdtm\define.xml							
Generated: 2014-04-28T17:37:48							
Engine Version: 1.5							
MedDRA Version: 15.1							
CDISC Controlled Terminology Version: 2014-03-28							
Processed Sources							
Domain	Label	Class	Source	Records	Errors	Warnings	Notices
GLOBAL	Global Metadata	--	--	--	0	0	0
AE	Adverse Events	Events	ae.xpt	1191	14	233	5
CM	Concomitant Medications	Interventions	cm.xpt	7510	81	3	212
DM	Demographics	Special Purpose	dm.xpt	306	9	1	5
DS	Disposition	Events	ds.xpt	596	1	60	8
EX	Exposure	Interventions	ex.xpt	591	0	2	3
LB	Laboratory Tests Results	Findings	lb.xpt	59580	1790	18287	19361
MH	Medical History	Events	mh.xpt	1818	3	10	8
QS	Questionnaires	Findings	qs.xpt	121749	0	9	0
RELREC	Related Records	Relationship	relrec.xpt	234	237	234	0
SC	Subject Characteristics	Findings	sc.xpt	254	254	0	254
SE	Subject Elements	Special Purpose	se.xpt	752	3	2	1
SUPPAE	Supplemental Qualifiers for AE	Relationship	suppae.xpt	1191	4	1	0
SUPPDM	Supplemental Qualifiers for DM	Relationship	suppdm.xpt	1197	4	1	0
SUPPDS	Supplemental Qualifiers for DS	Relationship	suppds.xpt	3	4	1	0
SUPPLB	Supplemental Qualifiers for LB	Relationship	supplb.xpt	64403	64407	64404	0
SV	Subject Visits	Special Purpose	sv.xpt	3559	0	3	0
TA	Trial Arms	Trial Design	ta.xpt	8	5	0	0
TE	Trial Elements	Trial Design	te.xpt	7	5	0	0
TI	Trial Inclusion/ Exclusion Criteria	Trial Design	ti.xpt	31	1	1	1
TS	Trial Summary	Trial Design	ts.xpt	33	9	14	8
TV	Trial Visits	Trial Design	tv.xpt	21	3	2	1
VS	Vital Signs	Findings	vs.xpt	29643	3	1	0
Total				294677	66837	83269	19867
Unprocessed Sources							
Domain	Label	Class	Reason		Errors	Warnings	Notices
Total					0	0	0
Grand Total				294677	66837	83269	19867

OpenCDISC Validator Report (3)

Issue Summary

- The **Issues Summary** tab provides a break down of the type of rules that have issues and how many have been reported.

OpenCDISC Validator Report				
Configuration: C:\opencdisc-validator_1_5\config\config-sdtm-3.1.2.xml				
Define.xml: C:\work\updated_pilot_submission_package\Updated Pilot Submission Package\900172\m5\datasets\cdiscpilot01\tabulations\sdtm\define.xml				
Generated: 2014-04-28T17:37:48				
Engine Version: 1.5				
MedDRA Version: 15.1				
CDISC Controlled Terminology Version: 2014-03-28				
Issue Summary				
Source	Rule ID	Message	Severity	Found
AE				
	SD0058	Variable appears in dataset, but is not in SDTM standard	Error	10
	SD1082	AEACN variable length is too long for actual data	Error	1
	SD1082	AEDECOD variable length is too long for actual data	Error	1
	SD1082	AEOU variable length is too long for actual data	Error	1
	SD1082	AETERM variable length is too long for actual data	Error	1
	SD1077	FDA Expected variable not found	Warning	1
	SD1083	Missing AEDY variable, when AEDTC variable is present	Warning	1
	SD1090	Incorrect value for AESTDY variable	Warning	1
	SD1201	Duplicate records	Warning	230
	SD1076	Model permissible variable added into standard domain	Notice	1
	SKIP_SD0008	C:\opencdisc-validator_1_5\config\data\MedDRA/8.0/pt.asc is missing or lacks necessary variables and cannot be used for this cross-dataset validation	Notice	1
	SKIP_SD0008	C:\opencdisc-validator_1_5\config\data\MedDRA/8.0/pt.asc is missing or lacks necessary variables and cannot be used for this cross-dataset validation	Notice	1
	SKIP_SD1114	C:\opencdisc-validator_1_5\config\data\MedDRA/8.0/soc.asc is missing or lacks necessary variables and cannot be used for this cross-dataset validation	Notice	1
	SKIP_SD1114	C:\opencdisc-validator_1_5\config\data\MedDRA/8.0/soc.asc is missing or lacks necessary variables and cannot be used for this cross-dataset validation	Notice	1
CM				
	SD0035	Missing value for CMDOSU, when CMDOSE, CMDOSTXT or CMDOSTOT is provided	Error	80
	SD1082	CMROUTE variable length is too long for actual data	Error	1
	SD1077	FDA Expected variable not found	Warning	1
	SD1081	CMDOSU variable length is too long for actual data	Warning	1
	SD1083	Missing CMDY variable, when CMDTC variable is present	Warning	1
	CT0018	Value for CMDOSFRQ not found in (FREQ) CT codelist	Notice	192
	CT0049	Value for CMDOSU not found in (UNIT) CT codelist	Notice	16
	SD1076	Model permissible variable added into standard domain	Notice	4

OpenCDISC Validator Report (4)

Details

- The Details tab provides detailed information about errors and warnings

Domain	Record	Count	Variables	Values	Rule ID	Message	Category	Severity
GLOBAL			DOMAIN	SE	SD1111	Missing SE dataset	Presence	Warning
GLOBAL			DOMAIN	TA	SD1112	Missing TA dataset	Presence	Warning
GLOBAL			DOMAIN	TE	SD1113	Missing TE dataset	Presence	Warning
AE			VARIABLE, DATASET	EPOCH, AE	SD1077	FDA Expected variable not found	Metadata	Warning
AE		15	AEOUT	NOT RESOLVED	CT0027	Value for AEOUT not found in (OUT) CT codelist	Terminology	Error
AE			Variable, Excess	AESEV, 12	SD1081	AESEV variable length is too long for actual data	Metadata	Warning
AE			Variable, Excess	AEREFID, 8	SD1081	AEREFID variable length is too long for actual data	Metadata	Warning
AE			Variable, Excess	AEENDTC, 10	SD1081	AEENDTC variable length is too long for actual data	Metadata	Warning
AE			Variable, Excess	AEACN, 9	SD1081	AEACN variable length is too long for actual data	Metadata	Warning
AE			Variable, Excess	AESPID, 18	SD1081	AESPID variable length is too long for actual data	Metadata	Warning
AE			Variable, Excess	AESTDTC, 10	SD1081	AESTDTC variable length is too long for actual data	Metadata	Warning
AE			Variable, Excess	DOMAIN, 6	SD1081	DOMAIN variable length is too long for actual data	Metadata	Warning
AE			Variable, Excess	AEENTPT, 31	SD1082	AEENTPT variable length is too long for actual data	Metadata	Error
AE			Variable, Excess	AETERM, 46	SD1082	AETERM variable length is too long for actual data	Metadata	Error
AE			Variable, Excess	AEOUT, 38	SD1082	AEOUT variable length is too long for actual data	Metadata	Error
AE			Variable, Excess	AEBODSYS, 148	SD1082	AEBODSYS variable length is too long for actual data	Metadata	Error
AE			Variable, Excess	AEDECOD, 161	SD1082	AEDECOD variable length is too long for actual data	Metadata	Error
AE			Variable, Excess	AEENRTPT, 33	SD1082	AEENRTPT variable length is too long for actual data	Metadata	Error
AE	8		AESER	Y	SD0009	No qualifiers set to "Y", when AE is Serious	Consistency	Warning
AE	18		AESER	Y	SD0009	No qualifiers set to "Y", when AE is Serious	Consistency	Warning
AE	30		AESER	Y	SD0009	No qualifiers set to "Y", when AE is Serious	Consistency	Warning
AE	41		AESER	Y	SD0009	No qualifiers set to "Y", when AE is Serious	Consistency	Warning
AE	68		AESER	Y	SD0009	No qualifiers set to "Y", when AE is Serious	Consistency	Warning
AE	69		AESER	Y	SD0009	No qualifiers set to "Y", when AE is Serious	Consistency	Warning
AE	84		AETERM	ACCIDENTAL FALL RESULTING IN SUPERFICIAL LAYERS OF HEAD INJURY	SD1021	Unexpected character value in AETERM variable	Format	Warning
				ACCIDENTAL FALL RESULTING IN SUPERFICIAL LAYERS OF HEAD INJURY				

OpenCDISC Validator Report (5)

Rules

- Contains a list of Rule IDs and their descriptions
- The links to each rule ID in the Issues Summary and Details worksheets take you to this worksheet

CT

Rule ID	Message	Description	Category	Severity
CT0001	Value for --ACN not found in (ACN) CT codelist	Action Taken with Study Treatment (--ACN) variable values must be populated with terms found in 'Action Taken with Study Treatment' (C66767) CDISC controlled terminology codelist. New values cannot be added into the CDISC CT non-extensible codelist.	Terminology	Error
CT0002	Value for AESEV not found in (AESEV) CT codelist	Severity/Intensity (AESEV) variable values must be populated with terms found in 'Severity/Intensity Scale for Adverse Events' (C66769) CDISC controlled terminology codelist. New values cannot be added into the CDISC CT non-extensible codelist.	Terminology	Error
CT0003	Value for TSVAL not found in (AGESPAN) CT codelist	TS dataset Parameter Value (TSVAL) values should be populated with terms found in 'Age Span' (C66780) CDISC controlled terminology codelist, when Trial Summary Parameter Short Name (TSPARMCD) value is 'AGESPAN'. New terms can be added as long as they are not duplicates, synonyms or subsets of existing standard terms.	Terminology	Information
CT0004	Value for AGEU not found in (AGEU) CT codelist	Age Units (AGEU) variable values must be populated with terms found in 'Age Unit' (C66781) CDISC controlled terminology codelist. New values cannot be added into the CDISC CT non-extensible codelist.	Terminology	Error
CT0005	Value for TSVAL not found in (AGEU) CT codelist	TS dataset Parameter Value (TSVAL) values must be populated with terms found in 'Age Unit' (C66781) CDISC controlled terminology codelist, when Trial Summary Parameter Short Name (TSPARMCD) value is 'AGEU'. New values cannot be added into the CDISC CT non-extensible codelist.	Terminology	Error
CT0006	Value for COUNTRY not found in (COUNTRY) CT codelist	Country (COUNTRY) variable values must be populated with terms found in 'Country' (C66786) CDISC controlled terminology codelist. New values cannot be added into the CDISC CT non-extensible codelist.	Terminology	Error

SD

A	B	C	D	E
Rule ID	Message	Description	Category	Severity
SD0001	No records in data source	Domain table should have at least one record	Presence	Warning
SD0002	NULL value in -- variable marked as Required	Required variables (where Core attribute is 'Req') cannot be NULL for any records	Presence	Error
SD0003	Invalid ISO 8601 value for -- variable	Value of Dates/Time variables (*DTC) must conform to the ISO 8601 international standard	Format	Error
SD0004	Inconsistent value for DOMAIN	Domain Abbreviation (DOMAIN) variable should be consistent with the name of the dataset	Consistency	Warning
SD0005	Duplicate value for --SEQ variable	The value of Sequence Number (--SEQ) variable must be unique for each record within a domain and within of Unique Subject Identifier (USUBJID) or Pool Identifier (POOLID) variables value when they are present in the domain.	Consistency	Error
SD0006	No baseline result in -- for subject	All subjects should have at least one baseline observation (--BLFL = 'Y') in EG, LB, MB, MS, PC and VS domains, except for subjects who failed screening (ARMCD = 'SCRNFAL') or were not fully assigned to an Arm (ARMCD = 'NOTASSGN') or were not treated (ACTARMCD = 'NOTTRT')	Presence	Warning
		Standard Units (--STRFSU) must be consistent for all records with same Short Name of		

How to Interpret the Errors/Warnings (1)

Issue Summary Tab

Issue Summary				
Source	Rule ID	Message	Severity	Found
AE	CT0027	Value for AEOUT not found in (OUT) CT codelist	Error	274
	SD1082	AEBODSYS variable length is too long for actual data	Error	1
	SD1082	AEDECOD variable length is too long for actual data	Error	1
	SD1082	AEENRTPT variable length is too long for actual data	Error	1
	SD1082	AEENTPT variable length is too long for actual data	Error	1
	SD1082	AEOUT variable length is too long for actual data	Error	1

Details Tab

Domain	Record	Count	Variables	Values	Rule ID	Message	Category	Severity
AE		15	AEOUT	NOT RESOLVED	CT0027	Value for AEOUT not found in (OUT) CT codelist	Terminology	Error
AE		259	AEOUT	STOPPED	CT0027	Value for AEOUT not found in (OUT) CT codelist	Terminology	Error

Rules Tab

CT0027	Value for --OUT not found in (OUT) CT codelist	Outcome (--OUT) variables values must be populated with terms found in 'Outcome of Event' (C66768) CDISC controlled terminology codelist. New values cannot be added into the CDISC CT non-extensible codelist.	Terminology	Error
--------	--	---	-------------	-------

Terminology

C66768	OUT	Outcome of Event	A condition or event that is attributed to the adverse event and is the result or conclusion of the adverse event. (NCI)	No
--------	-----	------------------	--	----

The allowed values for AEOUT are:

- FATAL, NOT RECOVERED/NOT RESOLVED, RECOVERED/RESOLVED, RECOVERED/RESOLVED WITH SEQUELAE, RECOVERING/RESOLVING and UNKNOWN

How to Interpret the Errors/Warnings (2)

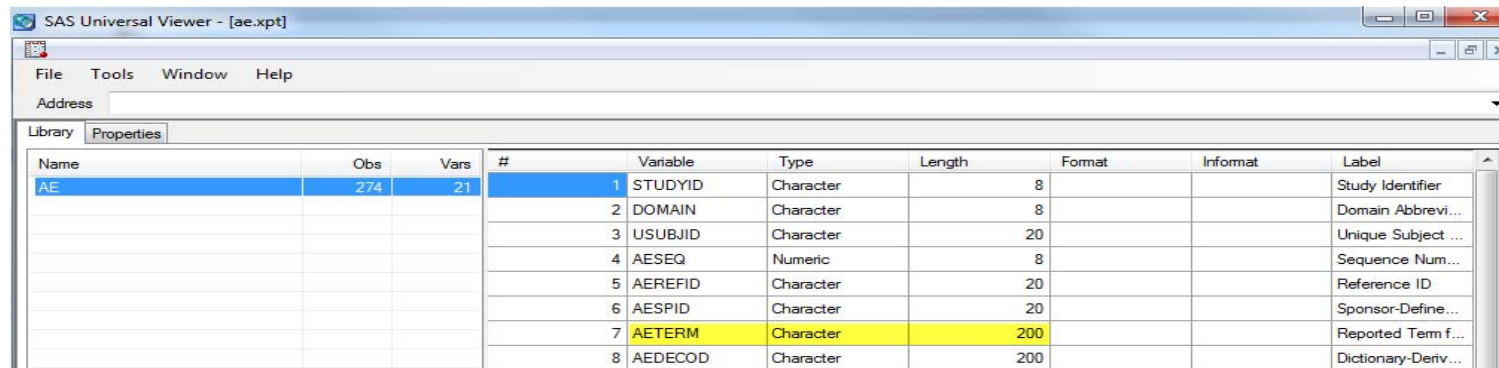
■ Issue Summary Tab

Source	Rule ID	Message	Severity	Found
AE				
	CT0027	Value for AEOUT not found in (OUT) CT codelist	Error	274
	SD1082	AEBODSYS variable length is too long for actual data	Error	1
	SD1082	AEDECOD variable length is too long for actual data	Error	1
	SD1082	AEENRTPT variable length is too long for actual data	Error	1
	SD1082	AEENTPT variable length is too long for actual data	Error	1
	SD1082	AEOUT variable length is too long for actual data	Error	1
	SD1082	AETERM variable length is too long for actual data	Error	1
	SD0009	No qualifiers set to "Y", when AE is Serious	Warning	10

■ Details Tab

Domain	Record	Count	Variables	Values	Rule ID	Message	Category	Severity
AE			Variable, Excess	AEBODSYS, 148	SD1082	AEBODSYS variable length is too long for actual data	Metadata	Error
AE			Variable, Excess	AETERM, 46	SD1082	AETERM variable length is too long for actual data	Metadata	Error
AE	170		USUBJID, AESTDTC	8HA02PED-587-603, 2012-12-17	SD0080	AE start date is after the latest Disposition date	Consistency	Warning

■ AE Dataset



The screenshot shows the SAS Universal Viewer interface for a dataset named 'ae.xpt'. The 'Library' tab is selected, displaying a table with columns: Name, Obs, Vars, #, Variable, Type, Length, Format, Informat, and Label. The dataset 'AE' is highlighted, showing 274 observations and 21 variables. The variable list includes STUDYID, DOMAIN, USUBJID, AESEQ, AREFID, AESPID, AETERM, and AEDECOD. The 'AETERM' variable is highlighted in yellow, showing a length of 200.

Name	Obs	Vars	#	Variable	Type	Length	Format	Informat	Label
AE	274	21	1	STUDYID	Character	8			Study Identifier
			2	DOMAIN	Character	8			Domain Abbrevi...
			3	USUBJID	Character	20			Unique Subject ...
			4	AESEQ	Numeric	8			Sequence Num...
			5	AREFID	Character	20			Reference ID
			6	AESPID	Character	20			Sponsor-Define...
			7	AETERM	Character	200			Reported Term f...
			8	AEDECOD	Character	200			Dictionary-Deriv...

How to Interpret the Errors/Warnings (3)

Issue Summary Tab

CE				
SD0037	Value for CECAT not found in (CECAT) user-defined codelist	Error	9	
SD1082	CECAT variable length is too long for actual data	Error	1	
SD1082	CESCAT variable length is too long for actual data	Error	1	
SD1082	CETERM variable length is too long for actual data	Error	1	
SD1077	FDA Expected variable not found	Warning	1	

Details Tab

A	B	C	D	E	F	G	H	I
Domain	Record	Count	Variables	Values	Rule ID	Message	Category	Severity
CE			VARIABLE, DATASET	EPOCH, CE	SD1077	FDA Expected variable not found	Metadata	Warning
CE			VARIABLE	CESTDY	SD1087	Missing CESTDY variable, when CESTDTC variable is present	Presence	Warning
CE		5	CECAT	INTERNAL	SD0037	Value for CECAT not found in (CECAT) user-defined codelist	Terminology	Error
CE		4	CECAT	JOINT	SD0037	Value for CECAT not found in (CECAT) user-defined codelist	Terminology	Error
CE			Variable, Excess	DOMAIN, 6	SD1081	DOMAIN variable length is too long for actual data	Metadata	Warning
CE			Variable, Excess	CECAT, 89	SD1082	CECAT variable length is too long for actual data	Metadata	Error

Dataset Values

CECAT
INTERNAL
JOINT
MUSCLE
SKIN/MUCOSA

Define Values

Code Value
INTERNAL_TEST
JOINT_TEST
MUSCLE
SKIN/MUCOSA

How to Interpret the Errors/Warnings (4)

Issue Summary Tab

Source	Rule ID	Message	Severity	Found
DEFINE				
	DD0024	Invalid Codelist for 'AECONTRT' variable	Error	1
	DD0024	Invalid Codelist for 'AESER' variable	Error	1
	DD0024	Invalid Codelist for 'AESEV' variable	Error	1
	DD0024	Invalid Codelist for 'XRBLFL' variable	Error	1
	OD0048	Referenced 'CodeList' not found	Error	2

Details Tab

xpath	Variables	Values	Rule ID	Message	Category	Severity
//ItemDef[@OID='DM.SEX']/CodeListRef[@CodeListOID='SEX']	@CodeListOID	SEX	OD0048	Referenced 'CodeList' not found	Cross-reference	Error
//ItemDef[@OID='IE.IETESTCD']/CodeListRef[@CodeListOID='IETESTCD']	@CodeListOID	IETESTCD	OD0048	Referenced 'CodeList' not found	Cross-reference	Error

Define

SEX	Sex	text	SEX 	CRF Page 8	Record Qualifier	
-----	-----	------	--	----------------------------	----------------------------------	--

Do All Errors/Warnings Need to Be Fixed? (1)

- Errors and warnings that **CAN** be fixed, **SHOULD** be fixed
 - **Define** : All Validation issues should be fixed
 - **Data**: Talk to your Standards group, here are some examples that should be fixed

Rule ID	Message
SD0002	NULL value in variable marked as Required
SD0056	SDTM Required variable not found
SD0059	Define.xml/dataset variable type mismatch
SD1005	Invalid STUDYID
SD1029	Non-ASCII or non-printable characters

Do All Errors/Warnings Need to Be Fixed? (2)

- Errors and warnings that **can't be fixed**, should be **documented and explained** in the Reviewer's Guide:

Rule ID	Message	Explanation
SD0087	RFSTDTC is not provided for a randomized subject	The subject is randomized in error, or the subject has been randomized but never received any study treatment
SD0013	Begin day must be less than or equal to end day	This error often appears for the Conmeds domain (CM), where a conmed has a partial start date (CMSTDTC) and a complete end date (CMENDTC).
SD0006	No baseline result in XX for subject	The subject is randomized but not dosed

How to Document Validation Issues (1)

- Document and explain all validation issues that cannot be eliminated in the Data Conformance Summary section of the reviewer's guide ([SDRG PhUSE Template](#)).

Study Data Reviewer's Guide

<Sponsor Name>
Study <Protocol Number>
Version 2013-05-13

Study Data Reviewer's Guide

Contents

1. Introduction	3
1.1 Purpose	3
1.2 Acronyms	3
1.3 Study Data Standards and Dictionary Inventory	3
2. Protocol Description	3
2.1 Protocol Number and Title	3
2.2 Protocol Design	4
2.3 Trial Design Datasets	4
2.3.1. TA – Trial Arms	4
2.3.2. TE – Trial Elements	4
2.3.3. TV – Trial Visits	4
2.3.4. TI – Trial Inclusion/Exclusion Criteria	4
2.3.5. TS – Trial Summary	4
3. Subject Data Description	5
3.1 Overview	5
3.2 Annotated CRFs	5
3.3 SDTM Subject Domains	6
3.3.1. AE – Adverse Events	6
3.3.2. DS – Disposition	6
3.3.3. EX – Exposure	6
3.3.4. Dataset – Dataset Label	6
4. Data Conformance Summary	7
4.1 Conformance Inputs	7
4.2 Issues Summary	7
4.3 Additional Conformance Details	8
Appendix I: Inclusion/Exclusion Criteria	9
Appendix II: Conformance Issues Details	10

I

How to Document Validation Issues (2)

- Create two tables, one for errors and one for warnings:

Rule ID	Domain	Compliance Check Description	Rationale
SD0087	DM	RFSTDTC is not provided for a randomized subject	The subject is randomized in error, or The subject has been randomized but never received any study treatment.
SD0013	CM	Begin day must be less than or equal to end day	The start date (CMSTDTC) has been recorded as a partial date and the end date (CMENDTC) as complete date.

Conclusion

- OpenCDISC Validator is a free and easy-to-use tool
- Used universally throughout the industry and by regulatory agencies
- Integrate OpenCDISC Validator in your data management, programming and CRO deliverables processes
- Need to build expertise on how to interpret and fix validation issues
- Fix all issues that CAN be fixed
- Explain issues that CAN NOT be fixed or are not applicable in Study Reviewer's Data Guide

Join us for the first ever OpenCDISC Live Forum



Register at OpenCDISC.org

Thank you!

Majdoub Haloui

Biogen Idec

Majdoub.haloui@biogenidec.com