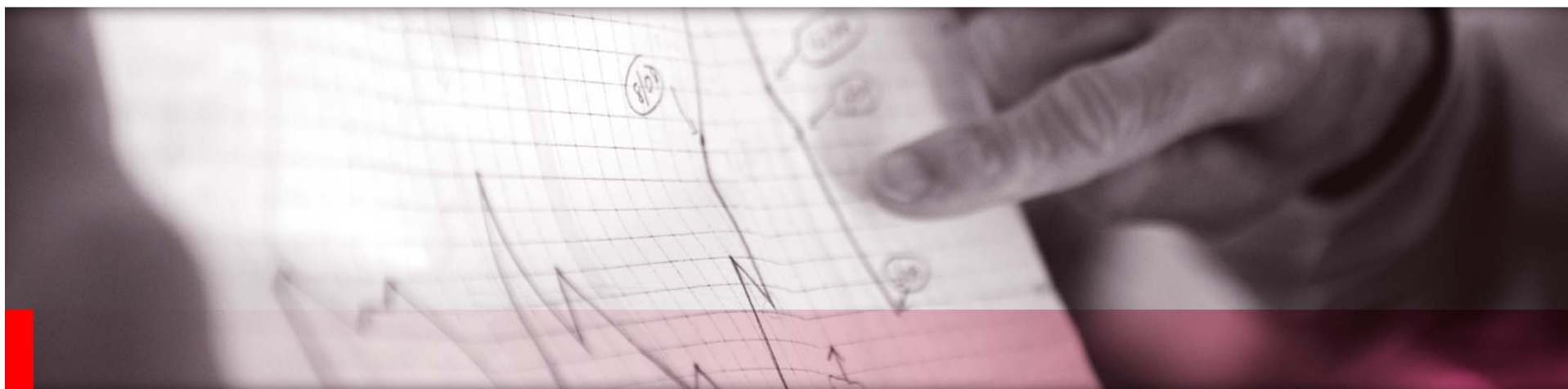




Using OpenCDISC in an Outsourced Model

Paul Bukowiec

Steve Wong

PhUSE Boston 2014-05-07

Takeda Pharmaceuticals International Co.

OpenCDISC in an outsourced model



- 3 CRO partners
- Standards group provides specifications for deliverables
 - SDTM-like tabulations
- Standards group provides **custom** OpenCDISC configuration files
 - Validation rules
 - SDTM-like metadata
 - Controlled Terminology
- Data Management group receives tabulations deliverables
 - Validates deliverable

What is OpenCDISC?



<http://www.opencdisc.org/about-opencdisc>



About OpenCDISC

OpenCDISC is an open source community focused on building extensible frameworks and tools for the implementation and advancement of CDISC Standards

How it came about

Industry adoption of CDISC has been on the rise with the availability of mature standards, implementation guides, training, and user groups. However, there has been very little help for the developers who are tasked with implementing the standards at their companies. There are currently very few tools, with most being too expensive and limited in functionality, which results in many companies developing custom solutions. CDISC success is largely due to the open, collaborative, and vendor-neutral process by which it was developed. We want to extend this process to the developers.

Community goals

Our primary goal is to provide a collaborative environment where developers, data managers, statisticians, and regulators can jointly discuss, identify, and develop tools for the advancement and implementation of CDISC standards. Our initial project is to develop the CDISC Validator, a tool aimed at ensuring compliance with various CDISC models including SDTM, ADaM, ODM and LAB. Future projects will focus on mapping and integration tools, but ultimately it's up to the community members to determine the direction.

What is OpenCDISC in an Outsourced Model?



<http://www.takeda.com/standards-opencdisc> (fake)



About OpenCDISC @ Takeda Boston

OpenCDISC @ Takeda Boston is a customizable tool where we can validate CRO deliverables against our CDISC-like Standards

How it came about

Although we are adopting a linear CDISC standards implementation strategy, we understand that change management at the operational level is critical to its success. As a result, we currently utilize an SDTM +/- model for our tabulation dataset specifications. However, we do utilize fundamental CDISC metadata management and definition best practices as part of our strategy. When looking to develop an in house tool to evaluate data standards compliance of CRO tabulation dataset deliverables, we realized our development approach allowed us to use OpenCDISC with slight modification.

Takeda goals

Our goal is to use standards metadata and OpenCDISC to assess compliance, identify implementation challenges, develop performance dashboards, increase efficiency, and ultimately transition to a more complete CDISC implementation strategy.

Validation Rules

Configurations

- SDTM 3.1.3
- SDTM 3.1.2
- SDTM 3.1.1
- Define.xml 2.0
- Define.xml 1.0
- ADaM 1.0
- SEND 3.0

Rule type

- Match Rule
- Unique Rule
- Regular Expression Rule
- Conditional Rule
- Required-When Rule
- Lookup Rule
- Metadata Rule

Category

- <Any>
- <Any>
- Consistency
- Cross-reference
- Format
- Limit
- Metadata
- Presence
- Structure
- System
- Terminology

Severity

- <Any>
- <Any>
- Error
- Warning
- Notice

Rule ID	Message	Description	Domain	Category	Severity
CT0001	Value for --ACN not found in (ACN) CT codelist	Action Taken with Study Treatment (--ACN) variable values should be populated with terms found in 'Action Taken with Study Treatment' (C66767) CDISC controlled terminology codelist	AE	Terminology	Warning
CT0002	Value for AESEV not found in (AESEV) CT codelist	Severity/Intensity (AESEV) variable values should be populated with terms found in 'Severity/Intensity Scale for Adverse Events' (C66769) CDISC controlled terminology codelist	AE	Terminology	Warning
CT0027	Value for --OUT not found in (OUT) CT codelist	Outcome (--OUT) variables values should be populated with terms found in 'Outcome of Event' (C66768) CDISC controlled terminology codelist	AE	Terminology	Warning
CT0044	Value for AETOXGR not found in (TOXGR) CT codelist	Standard Toxicity Grade (AETOXGR) variable values should be populated with terms found in 'Common Terminology Criteria for Adverse Events V4.0' (C87162) CDISC controlled terminology codelist	AE	Terminology	Warning
SD0009	No qualifiers set to 'Y', when AE is Serious	When Serious Event (AESER) variable value is 'Y', then at least one of seriousness criteria variables is expected to have value 'Y' (Involves Cancer (AESCAN), Congenital Anomaly or Birth Defect (AESCONG), Persist or Signif Disability/Incapacity (AESDISAB)	AE	Consistency	Warning
SD0080	AE start date is after the latest Disposition date	Start Date/Time of Adverse Event (AESTDTC) should be less than or equal to the Start Date/Time of the latest Disposition Event (DSSTDTC)	AE	Consistency	Warning
SD0090	AESDTH is not 'Y', when AEOUT='FATAL'	Results in Death (AEDTH) should equal 'Y', when Outcome of Adverse Event (AEOUT) is 'FATAL'	AE	Consistency	Warning
SD0091	AEOUT is not 'FATAL', when AESDTH='Y'	Outcome of Adverse Event should equal 'FATAL', when Results in Death (AEDTH) is 'Y'	AE	Consistency	Warning

Rule types (programming language-like syntax)



Type	Description
Match	Checks values against a list of hardcoded terms
Unique	Checks a list of variables for primary key uniqueness
Regular Expression	Checks values that fit a pattern (e.g. ISO-8601 date)
Conditional	Build a condition to check values: <i>variable <operator> variable or value</i>
Required-When	Checks value is non-null (when condition is met)
Lookup	Similar to Match but uses an alternate file for terms
Metadata	Checks alternate file for metadata conformity

Rule categories (a way to organize the rules)



Category	Description
Consistency	Between 2+ variables in same domain, sometimes used for uniqueness of non key variables
Cross-reference	Between variables in 2 domains
Format	Length checks (8, 40, 20), ISO -8601 date, outside 32-127 ASCII code, leading blanks
Limit	Start before end, high greater than low, no negative age or dose
Metadata	Non recommended length, Core (Req, Exp, Extra), Type
Presence	Empty domain, subject not in DS or EX, (--BLFL = 'Y') in EG, FA, LB, QS, and VS
Structure & System	Not used in SDTM
Terminology	Selected variables controlled by CDISC/NCI terms, select variables controlled by MedDRA terms

SDTM 3.1.2 rules copied by Takeda (1)



Rule ID	Description
SD0002	Required variables (where Core attribute is 'Req') cannot be NULL for any records
SD0003	Dates and times of day must conform to the ISO 8601 international standard
SD0018	The value of a Short Name of Measurement, Test or Examination (--TESTCD) variable should be limited to 8 characters, cannot start with a number, and cannot contain characters other than letters in upper case, numbers, or underscores
SD0055	Variable Data Types in the dataset should match the variable data types described in mSDTM
SD0056	Variables described in mSDTM as Required must be included in the dataset
SD0057	Variables described in mSDTM as Expected should be included in the dataset

SDTM 3.1.2 rules copied by Takeda (2)



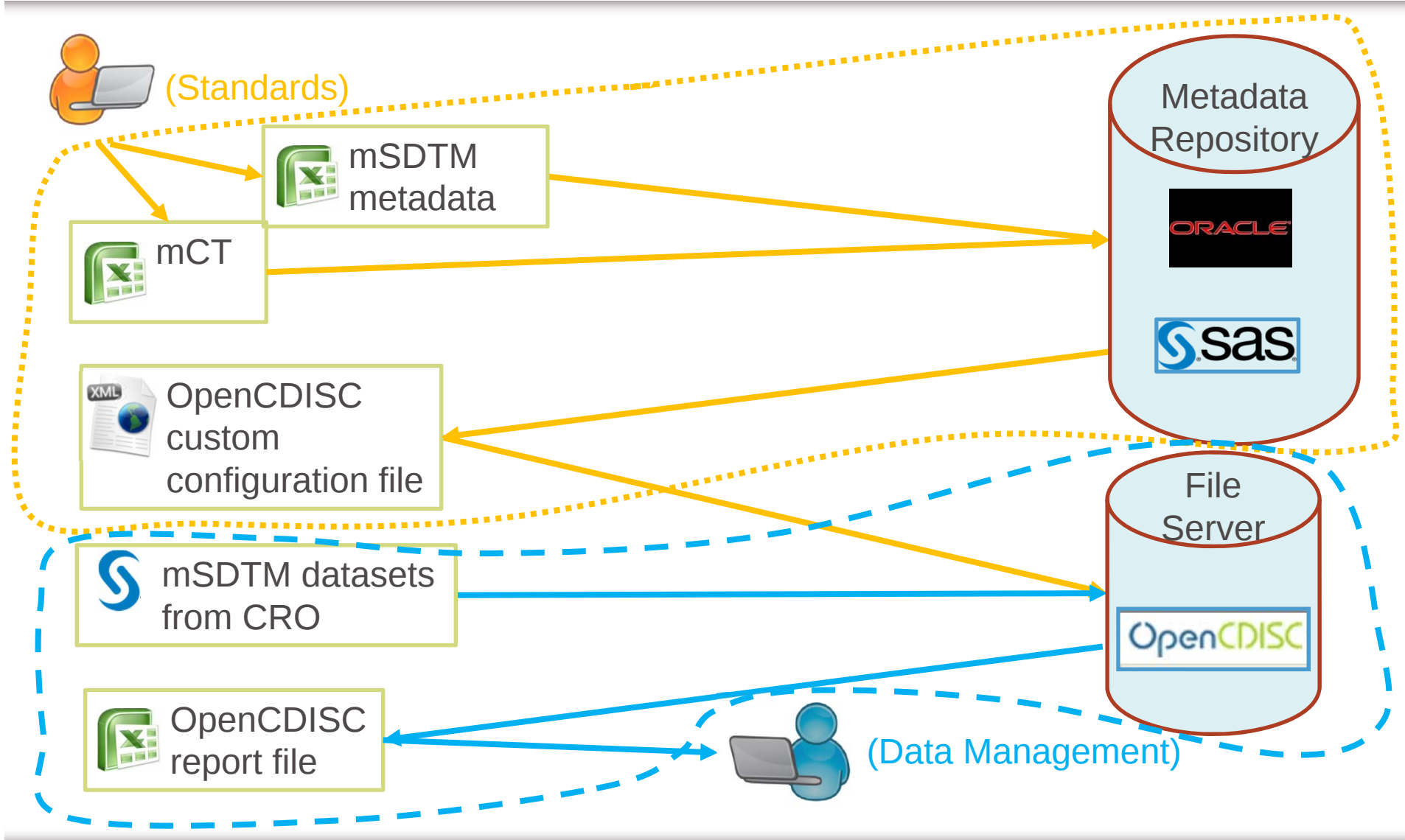
Rule ID	Description
SD0058	Only variables listed in mSDTM should appear in a dataset. New sponsor defined variables must not be added, and existing variables must not be renamed or modified
SD0063	Variable Label in the dataset should match the variable label described in mSDTM. When creating a new domain Variable Labels could be adjusted as appropriate to properly convey the meaning in the context of the data being submitted
SD0065	All Unique Subject Identifier (USUBJID) + Visit Name (VISIT) + Visit Number (VISITNUM) combination values in data should be present in the Subject Visits (SV) domain
SD1029	Variables value must not include non-ASCII or non-printable characters (outside of 32-127 ASCII code range), limited to variables which values may be converted into new variable name or label (--TEST, --TESTCD, --PARM, --PARMCD, QLABEL, QNAM)

New rules written by Takeda (this is the Open part)



Rule ID	Description
SD9001	Variable length in the dataset should match the variable length described in mSDTM for Text variables
SD9002, SD9004. SD9005, SD9006	The value of the variable cannot contain characters other than letters in upper case, numbers, or other printable characters (--TERM) (--CAT,--SCAT) (--REASND) (--NAM,--COM,--FAOBJ)
SD9003	Variable Label in the dataset must not include non-ASCII or non-printable characters (outside of 32-126 ASCII code range)
CT...	Variable values should be populated with terms found in MPI Global ePackage controlled terminology codelist

Process flow diagram



Configuration file



Follows ODM specifications

```
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.2"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns:xlink="http://www.w3.org/1999/xlink"
  xmlns:def="http://www.cdisc.org/ns/def/v1.0"
  xmlns:val="http://www.opencdisc.org/schema/validator"
  xsi:schemaLocation="http://www.cdisc.org/ns/odm/v1.2 resources/schema/validator1-0-0.xsd"
  FileType="Snapshot"
  FileOID="org.opencdisc.validator.sdtm.3.1.1.native"
  CreationDateTime="2009-06-09T19:06:27-04:00" ODMVersion="1.2"
  Originator="OpenCDISC.org">
  <Study OID="org.opencdisc.validator">
    <GlobalVariables>
      <StudyName>OpenCDISC Validator</StudyName>
      <StudyDescription>OpenCDISC Validator Configuration</StudyDescription>
      <ProtocolName>N/A</ProtocolName>
    </GlobalVariables>
```

Configuration file



```
<MetaDataVersion OID="CDISC.SDTM.3.1.1"
  Name="OpenCDISC Validator Configuration for CDISC SDTM v3.1.1 (Native)"
  Description="OpenCDISC Validator Configuration for CDISC SDTM v3.1.1 (Native)"
  def:DefineVersion="1.0.0"
  def:StandardName="CDISC SDTM"
  def:StandardVersion="3.1.1">
  <ItemGroupDef OID="domain"
    Name="domain"
    Repeating="repeating"
    IsReferenceData="isreferencedata"
    Purpose="purpose"
    def:Label="Label"
    def:Structure="structure"
    def:DomainKeys="domainkeys"
    def:Class="class"
    def:ArchiveLocationID="location">
    <ItemRef ItemOID="variable" Mandatory="mandatory" val:Core="corestatus"/>
    <val:ValidationRuleRef RuleID="ruleid" Active="active"/>
    <def:leaf ID="location" xlink:href="file">
      <def:title>file</def:title>
    </def:leaf>
  </ItemGroupDef>
  <ItemDef OID="variable" Name="variable" DataType="datatype" Length="length" def:Label="label">
  <val:ValidationRules>
    <val:RuleType Rule Attributes...>
  </val:ValidationRules>
</MetaDataVersion>
```

Configuration file (ItemGroup=dataset attributes)



```
- <ItemGroupDef OID="DM" Name="DM" Repeating="No" IsReferenceData="No" Purpose="Tabulation" def:Label="Demographics
  subject" def:DomainKeys="STUDYID, USUBJID" def:Class="Special Purpose" def:ArchiveLocationID="Location.DM">
  <!-- ***** -->
  <!-- Each variable is listed here for this ItemGroupDef (domain) -->
  <!-- ***** -->
  <ItemRef ItemOID="STUDYID" OrderNumber="1" Mandatory="Yes" Role="Identifier" val:Core="Required" />
  <ItemRef ItemOID="DOMAIN" OrderNumber="2" Mandatory="Yes" Role="Identifier" val:Core="Required" />
  <ItemRef ItemOID="USUBJID" OrderNumber="3" Mandatory="Yes" Role="Identifier" val:Core="Required" />
  <ItemRef ItemOID="SUBJID" OrderNumber="4" Mandatory="Yes" Role="Topic" val:Core="Required" />
  <ItemRef ItemOID="DM.RFSTDTC" OrderNumber="5" Mandatory="No" Role="Record Qualifier" val:Core="Expected" />
  <ItemRef ItemOID="DM.RFENDTC" OrderNumber="6" Mandatory="No" Role="Record Qualifier" val:Core="Expected" />
  <ItemRef ItemOID="DM.SITEID" OrderNumber="7" Mandatory="Yes" Role="Record Qualifier" val:Core="Required" />
  <ItemRef ItemOID="DM.INVID" OrderNumber="8" Mandatory="No" Role="Record Qualifier" val:Core="Permissible" />
  <ItemRef ItemOID="DM.INVNAM" OrderNumber="9" Mandatory="No" Role="Synonym Qualifier" val:Core="Permissible" />
  <ItemRef ItemOID="DM.BRTHDTC" OrderNumber="10" Mandatory="No" Role="Record Qualifier" val:Core="Permissible" />
  <ItemRef ItemOID="DM.AGE" OrderNumber="11" Mandatory="No" Role="Record Qualifier" val:Core="Expected" />
  <ItemRef ItemOID="DM.AGEU" OrderNumber="12" Mandatory="No" Role="Variable Qualifier" val:Core="Expected" />
  <ItemRef ItemOID="DM.SEX" OrderNumber="13" Mandatory="Yes" Role="Record Qualifier" val:Core="Required" />
  <ItemRef ItemOID="DM.RACE" OrderNumber="14" Mandatory="No" Role="Record Qualifier" val:Core="Expected" />
  <ItemRef ItemOID="DM.ETHNIC" OrderNumber="15" Mandatory="No" Role="Record Qualifier" val:Core="Permissible" />
  <ItemRef ItemOID="DM.ARMCD" OrderNumber="16" Mandatory="Yes" Role="Record Qualifier" val:Core="Required" />
  <ItemRef ItemOID="DM.ARM" OrderNumber="17" Mandatory="Yes" Role="Synonym Qualifier" val:Core="Required" />
  <ItemRef ItemOID="DM.COUNTRY" OrderNumber="18" Mandatory="Yes" Role="Record Qualifier" val:Core="Required" />
  <ItemRef ItemOID="DM.DMXFN" OrderNumber="19" Mandatory="No" Role="Record Qualifier" val:Core="Permissible" />
  <ItemRef ItemOID="DM.VISITNUM" OrderNumber="20" Mandatory="No" Role="Timing" val:Core="Permissible" />
  <ItemRef ItemOID="DM.VISIT" OrderNumber="21" Mandatory="No" Role="Timing" val:Core="Permissible" />
  <ItemRef ItemOID="DM.VISITDY" OrderNumber="22" Mandatory="No" Role="Timing" val:Core="Permissible" />
  <ItemRef ItemOID="DM.DMDTC" OrderNumber="23" Mandatory="No" Role="Timing" val:Core="Permissible" />
  <ItemRef ItemOID="DM.DMDY" OrderNumber="24" Mandatory="No" Role="Timing" val:Core="Permissible" />
```

Configuration file (Item=variable attributes)



```
<!-- ItemDef OID=DM.AGE Name=AGE DataType=integer Length=8 def:Label=Age --> />
<ItemDef OID="DM.AGE" Name="AGE" DataType="integer" Length="8" def:Label="Age" />
<ItemDef OID="DM.AGEU" Name="AGEU" DataType="text" Length="200" def:Label="Age Units" />
<ItemDef OID="DM.ARM" Name="ARM" DataType="text" Length="200" def:Label="Description of Planned Arm" />
<ItemDef OID="DM.ARMCD" Name="ARMCD" DataType="text" Length="20" def:Label="Planned Arm Code" />
<ItemDef OID="DM.BRTHDTC" Name="BRTHDTC" DataType="datetime" def:Label="Date/Time of Birth" />
<ItemDef OID="DM.COUNTRY" Name="COUNTRY" DataType="text" Length="3" def:Label="Country" />
<ItemDef OID="DM.DMDTC" Name="DMDTC" DataType="datetime" def:Label="Date/Time of Collection" />
<ItemDef OID="DM.DMDY" Name="DMDY" DataType="integer" Length="8" def:Label="Study Day of Collection" />
<ItemDef OID="DM.DMXFN" Name="DMXFN" DataType="text" Length="200" def:Label="External Filename" />
<ItemDef OID="DM.ETHNIC" Name="ETHNIC" DataType="text" Length="200" def:Label="Ethnicity" />
<ItemDef OID="DM.INVID" Name="INVID" DataType="text" Length="200" def:Label="Investigator Identifier" />
<ItemDef OID="DM.INVNAM" Name="INVNAM" DataType="text" Length="200" def:Label="Investigator Name" />
<ItemDef OID="DM.RACE" Name="RACE" DataType="text" Length="200" def:Label="Race" />
<ItemDef OID="DM.RFENDTC" Name="RFENDTC" DataType="datetime" def:Label="Subject Reference End Date/Time" />
<ItemDef OID="DM.RFSTDTC" Name="RFSTDTC" DataType="datetime" def:Label="Subject Reference Start Date/Time" />
<ItemDef OID="DM.SEX" Name="SEX" DataType="text" Length="1" def:Label="Sex" />
<ItemDef OID="DM.SITEID" Name="SITEID" DataType="text" Length="200" def:Label="Study Site Identifier" />
<ItemDef OID="DM.VISIT" Name="VISIT" DataType="text" Length="200" def:Label="Visit Name" />
<ItemDef OID="DM.VISITDY" Name="VISITDY" DataType="integer" Length="8" def:Label="Planned Study Day of Visit" />
<ItemDef OID="DM.VISITNUM" Name="VISITNUM" DataType="float" Length="10" def:Label="Visit Number" SignificantDigits="3" />
<ItemDef OID="DOMAIN" Name="DOMAIN" DataType="text" Length="2" def:Label="Domain Abbreviation" />
```

Configuration file (ItemGroup & Item using stylesheet)



Demographics				
Dataset Structure				
Variable	Description	Required	Data Type	Length
STUDYID	Study Identifier	✓	text	200
DOMAIN	Domain Abbreviation	✓	text	2
USUBJID	Unique Subject Identifier	✓	text	200
SUBJID	Subject Identifier for the Study	✓	text	200
RFSTDTC	Subject Reference Start Date/Time		datetime	200
RFENDTC	Subject Reference End Date/Time		datetime	200
SITEID	Study Site Identifier	✓	text	200
INVID	Investigator Identifier		text	200
INVNAM	Investigator Name		text	200
BRTHDTC	Date/Time of Birth		datetime	200
AGE	Age		integer	8
AGEU	Age Units		text	200
SEX	Sex	✓	text	1
RACE	Race		text	200
ETHNIC	Ethnicity		text	200
ARMCD	Planned Arm Code	✓	text	20
ARM	Description of Planned Arm	✓	text	200
COUNTRY	Country	✓	text	3

Configuration file (ValidationRules=Rule_Type syntax)



```
--
- <val:ValidationRules>
  <!-- ***** -->
  <!-- Janus Validation Rules -->
  <!-- ***** -->
  <val:Required ID="SD0002" Variable="%Variables.Core:Required%" Message="NULL value in variable marked as Required variables (where Core attribute is 'Req') cannot be NULL for any records" Category="Presence" Type="Error" />
  <val:Regex ID="SD0003" Variable="%Variables[*DTC]%" Test="%Variable.Type.Regex%" Message="Invalid ISO 8601 times of day must conform to the ISO 8601 international standard" Category="Format" Type="Error" />
  <val:Match ID="SD0004" Variable="DOMAIN" Terms="%Domain%" Delimiter="," Message="Inconsistent value for DOMAIN Abbreviation (DOMAIN) variable should be consistent with the name of the dataset" Category="Consistency" Type="Error" />
  <val:Unique ID="SD0005" Variable="%Domain%SEQ" GroupBy="USUBJID" When="%Domain%SEQ != ''" Message="Duplicate Description="The value of Sequence Number (--SEQ) variable must be unique for each record within a subject" Category="Error" Type="Error" />
  <val:Lookup ID="SD0006" Variable="USUBJID == USUBJID" From="%Domains[EG, LB, QS, VS]%" Where="%Domain.From" When="ARMCD @neqic 'SCRNFAIL' @and ARMCD @neqic 'NOTASSGN' @and USUBJID != ''" Message="No baseline observation for subject" Description="All subjects should have at least one baseline observation (--BLFL = 'Y') in EG, LB, QS, and subjects who failed screening (ARMCD = 'SCRNFAIL') or were not fully assigned to an Arm (ARMCD = 'NOTASSGN')" Category="Warning" Type="Warning" />
  <val:Unique ID="SD0007" Variable="%Domain%STRESU" GroupBy="%Domain%TESTCD,%Domain%CAT" Matching="Y" STRESU != ''" Message="Inconsistent value for Standard Units" Description="Standard Units (--STRESU) must be the same Short Name of Measurement, Test or Examination (--TESTCD) and Category (--CAT)" Category="Consistency" Type="Error" />
  <val:Lookup ID="SD0008" Variable="V2 == %Variables[%Domain%DECOD].CodeList.External%" From="FILE:DOLLAR\System.ConfigDirectory%/data/MedDRA/%Variable.CodeList.Version%/pt.asc" When="%Domain%DECOD != [%Domain%DECOD].Define.WithCodeList%" Message="Value for %Domain%DECOD not found in MedDRA dictionary the Dictionary-Derived Term (--DECOD) variable must be populated using a Preferred Term of the MedDRA dictionary the define.xml" Category="Terminology" Type="Error" />
```

Configuration file (ValidationRules using stylesheet)



Validation Rules

ID	Description	Validator	Message	Type	Severity	Active
SD0002	Required variables (where Core attribute is 'Req') cannot be NULL for any records	Required	NULL value in variable marked as Required	 Error		
SD0003	Dates and times of day must conform to the ISO 8601 international standard	Regex	Invalid ISO 8601 value	 Error		
SD0004	Domain Abbreviation (DOMAIN) variable should be consistent with the name of the dataset	Match	Inconsistent value for DOMAIN	 Warning		
SD0037	Variable values should be populated with terms found in the user-defined codelist associated with the variable in define.xml	Match	Value for %Variable% not found in (% Variable.CodeList.Name%) user-defined codelist	 Warning		
SD0055	Variable Data Types in the dataset should match the variable data types described in SDTM	Lookup	SDTM/dataset variable type mismatch	 Warning		

OpenCDISC sample output



A	B	C	D	E	F	G	H
OpenCDISC Validator Report							
Configuration: P:\ascolill_biostats\ssi\OpenCDISC\opencdisc-validator\config\config-mSDTM-V2.1.xml							
Define.xml: Not provided							
Generated: 2013-03-04T08:01:38							
Processed Sources							
Name	Label	Class	Source	Records	Errors	Warnings	Notices
AE	Adverse Events	Events	AE.xpt	20	1	4	0
CM	Concomitant Medications	Interventions	CM.xpt	60	0	1	0
DC	Disease Characteristics	Findings	DC.xpt	43	0	0	0
DM	Demographics	Special Purpose Domains	DM.xpt	10	20	0	0
DS	Disposition	Events	DS.xpt	9	0	0	0
EG	ECG Test Results	Findings	EG.xpt	15	0	0	0
FA	Findings About Events or Interventions	Findings	FA.xpt	75	31	75	0
HU	Healthcare Utilization	Findings	HU.xpt	21	0	4	0
LB	Laboratory Tests Results	Findings	LB.xpt	1336	1402	3	0
MH	Medical History	Events	MH.xpt	44	0	0	0
PD	Pharmacodynamic Data	Findings	PD.xpt	28	5	4	0
PT	Prior Therapies	Interventions	PT.xpt	66	17	3	0
QS	Questionnaires	Findings	QS.xpt	927	0	0	0
SC	Subject Characteristics	Findings	SC.xpt	28	0	0	0
SV	Subject Visits	Special Purpose Domains	SV.xpt	36	2	1	0
VS	Vital Signs	Findings	VS.xpt	153	0	0	0
Total				2871	1478	95	0

OpenCDISC sample detailed output



C	D	E	F	G	H	I	J	K
Coun	Variables	Values	Rule ID	Message	Category	Severity	MPI Comments	
3	FACAT	INVESTIGATOR RESPONSE ASSESSMENT	CTFACAT	Value for FACAT not found in (FACAT) CT codelist	Terminology	Error	Please update this to RESPONSE ASSESSMEN	
3	FAMETHOD	OBJECTIVE RESPONSE	CTFAMETHOD	Value for FAMETHOD not found in (FAMETHOD) CT codelist	Terminology	Error	FAMETHOD should be left blank; FAOBJ = OBJE	
25	FAMETHOD	PHOTOGRAPHY	CTFAMETHOD	Value for FAMETHOD not found in (FAMETHOD) CT codelist	Terminology	Error	ok	
2	LBREASND	AMENORRHEA POST HETEROLOGOUS STEM CELL TRANSPLANTATION	CTLBREASND	Value for LBREASND not found in (LBREASND) CT codelist	Terminology	Error	Does not match CT	
10	LBSTRESU	EU/dL	CTLBSTRESU	Value for LBSTRESU not found in (LBSTRESU) CT codelist	Terminology	Error	Does not match CT- Please review and consid	
20	LBSTRESU	Ratio	CTLBSTRESU	Value for LBSTRESU not found in (LBSTRESU) CT codelist	Terminology	Error	Does not match CT- Please review and confirm	
50	LBSTRESU	cells/uL	CTLBSTRESU	Value for LBSTRESU not found in (LBSTRESU) CT codelist	Terminology	Error	Does not match CT- Please review and consid	
20	LBSTRESU	g/dL	CTLBSTRESU	Value for LBSTRESU not found in (LBSTRESU) CT codelist	Terminology	Error	Does not match CT- Please review and consid	
11	LBSTRESU	mL/min	CTLBSTRESU	Value for LBSTRESU not found in (LBSTRESU) CT codelist	Terminology	Error	Ok- approved by governance 2/28/13	
12	LBTEST	% Lymphs	CTLBTEST	Value for LBTEST not found in (LBTEST) CT codelist	Terminology	Error	Does not match CT- Please review	
12	LBTEST	% 45+3+	CTLBTEST	Value for LBTEST not found in (LBTEST) CT codelist	Terminology	Error	Does not match CT	
12	LBTEST	% 45+3+4+8-	CTLBTEST	Value for LBTEST not found in (LBTEST) CT codelist	Terminology	Error	Does not match CT	
12	LBTEST	% 45+3+4+8-45RA+45RO-	CTLBTEST	Value for LBTEST not found in (LBTEST) CT codelist	Terminology	Error	Does not match CT	
12	LBTEST	% 45+3+4+8-45RA-45RO+	CTLBTEST	Value for LBTEST not found in (LBTEST) CT codelist	Terminology	Error	Does not match CT	
12	LBTEST	% 45+3+4-8+	CTLBTEST	Value for LBTEST not found in (LBTEST) CT codelist	Terminology	Error	Does not match CT	
12	LBTEST	% 45+3+4-8+45RA+45RO-	CTLBTEST	Value for LBTEST not found in (LBTEST) CT codelist	Terminology	Error	Does not match CT	
12	LBTEST	% 45+3+4-8+45RA-45RO+	CTLBTEST	Value for LBTEST not found in (LBTEST) CT codelist	Terminology	Error	Does not match CT	
12	LBTEST	% 45+3-16+56+	CTLBTEST	Value for LBTEST not found in (LBTEST) CT codelist	Terminology	Error	Does not match CT	
12	LBTEST	% 45+3-19+	CTLBTEST	Value for LBTEST not found in (LBTEST) CT codelist	Terminology	Error	Does not match CT	

- Data Management
 - Runs OpenCDISC using the **custom** configuration, metadata and codelist files along with the SAS transport delivered from the CRO
 - Communicates findings to CRO
 - Observed improvements over the life of a study
 - Observed improvements in new studies by CRO with previous studies
 - Study specific deviations need to be QCd manually
- Current Status
 - Pilot configuration uses 10 copied rules + 6 custom rules + all CT
 - Future expansion may copy entire set of rules
 - In use since beginning of 2013
 - Running on approx 40 protocols

Ordinary wheelchair



Custom wheelchair





Takeda Pharmaceuticals International Company