



OpenCDISC

OpenCDISC.org – an open source initiative delivering tools for validation of CDISC data

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What is OpenCDISC?

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

OpenCDISC Validator

- Facilitates compliance with all CDISC models
- Supports various versions of the standards
- Provides users with control over the validation rules
- Supports near-CDISC, SDTM+, and sponsor defined standards
- Easy to integrate with existing systems and processes
- Based on freely-available open source technologies

OpenCDISC.org

The screenshot shows the OpenCDISC.org website homepage. At the top left is the OpenCDISC logo. To the right is a search bar with the text "Search". Below the logo and search bar is a navigation menu with buttons for HOME, ABOUT, VALIDATOR, RULES, DOWNLOAD, CONTRIBUTE, FORUM, and CONTACT. The main content area is divided into three columns. The first column is titled "VALIDATOR FOR CDISC" and lists three features: "Open-source", "Fully Configurable", and "Validates SDTM and more", each preceded by a green checkmark. The second column is titled "VERSION 1.1 RELEASED!" and contains two links: "Download Validator" with a download icon and "Learn about Validator" with a right-pointing arrow icon. The third column is titled "VALIDATION RULES REPOSITORY" and contains the text "SDTM, ADaM, and other rules. Use and contribute to our open CDISC Validation Rules Repository." Below this is a "USER LOGIN" section with a key icon, a "LOG IN" button, and links for "Create new account" and "Request new password". To the right of the login section are two news items. The first is titled "PHUSE IS COMING TO BOSTON" and is dated "Posted Thu, 08/19/2010 - 14:20". The text describes the team's participation in a PhUSE Single Day Event (SDE) in Boston on September 28th, 2010. It includes links for "Login" or "register" to post comments and "Read more". The second news item is titled "OPENCDISC VALIDATOR 1.1 RELEASED" and is dated "Posted Wed, 06/02/2010 - 15:13". The text announces the availability of the OpenCDISC Validator 1.1 and includes a link to "Download OpenCDISC Validator 1.1 here". At the bottom of the page, there is a "SUBSCRIBE" button and the text "What's New in Version 1.1".

Validator Page

OpenCDISC Search

HOME ABOUT **VALIDATOR** DOWNLOAD CONTRIBUTE FORUM CONTACT

MAX

- » My account
- » Create content
- » Administer
- » Log out

SUPPORTED CDISC STANDARDS

- SDTM 3.1.1
- SDTM 3.1.2 (Beta 2)
- ADaM 1.0 (Beta 2)
- ODM 1.2.1 (Beta 2)
- Define.xml 1.0 (Beta 2)

VIEW EDIT

OpenCDISC Validator

The OpenCDISC Validator project aims to develop open source, freely available, and commercial-quality tools for ensuring clinical data compliance with CDISC standards including SDTM, ADaM, ODM, and LAB.

The Validator's key strength is its architecture that separates validation rules from application logic. The driver behind this design decision was to provide users the ability to keep up with evolving standards, sans the need to update and re-validate application logic. The validation rules are defined using XML-based validation framework with power to specify a wide range of rules and flexibility to support near-SDTM, SDTM+, ODM extensions, and even custom datasets.


Validator's Key Features

- » Metadata driven validation framework
- » All validation rules and messages in a single XML file
- » Janus and WebSDM v2.6 validation checks included
- » Different configurations for every study and stage of clinical data lifecycle
- » Create your own standards and share with partners
- » Validation engine developed in Java


DOCUMENTATION

- Installing OpenCDISC Validator
- Using OpenCDISC Validator
- OpenCDISC Validation Framework


Validation Rules Database



[HOME](#) [ABOUT](#) [VALIDATOR](#) [DOWNLOAD](#) [CONTRIBUTE](#) [FORUM](#) [CONTACT](#)

**MAX**

- » [My account](#)
- » [Create content](#)
- » [Administer](#)
- » [Log out](#)

**SUPPORTED CDISC STANDARDS**

- SDTM 3.1.1
- SDTM 3.1.2 (Beta 2)
- ADaM 1.0 (Beta 2)
- ODM 1.2.1 (Beta 2)
- Define.xml 1.0 (Beta 2)

CDISC SDTM 3.1.1 Validation Rules

The following is a listing of CDISC SDTM version 3.1.1 validation rules supported by OpenCDISC Validator. The list includes all Janus validation rules as defined in the Janus SDTM Validation Specification v.1 and 10 additional rules defined by the OpenCDISC community.

Domain: Type: Severity:

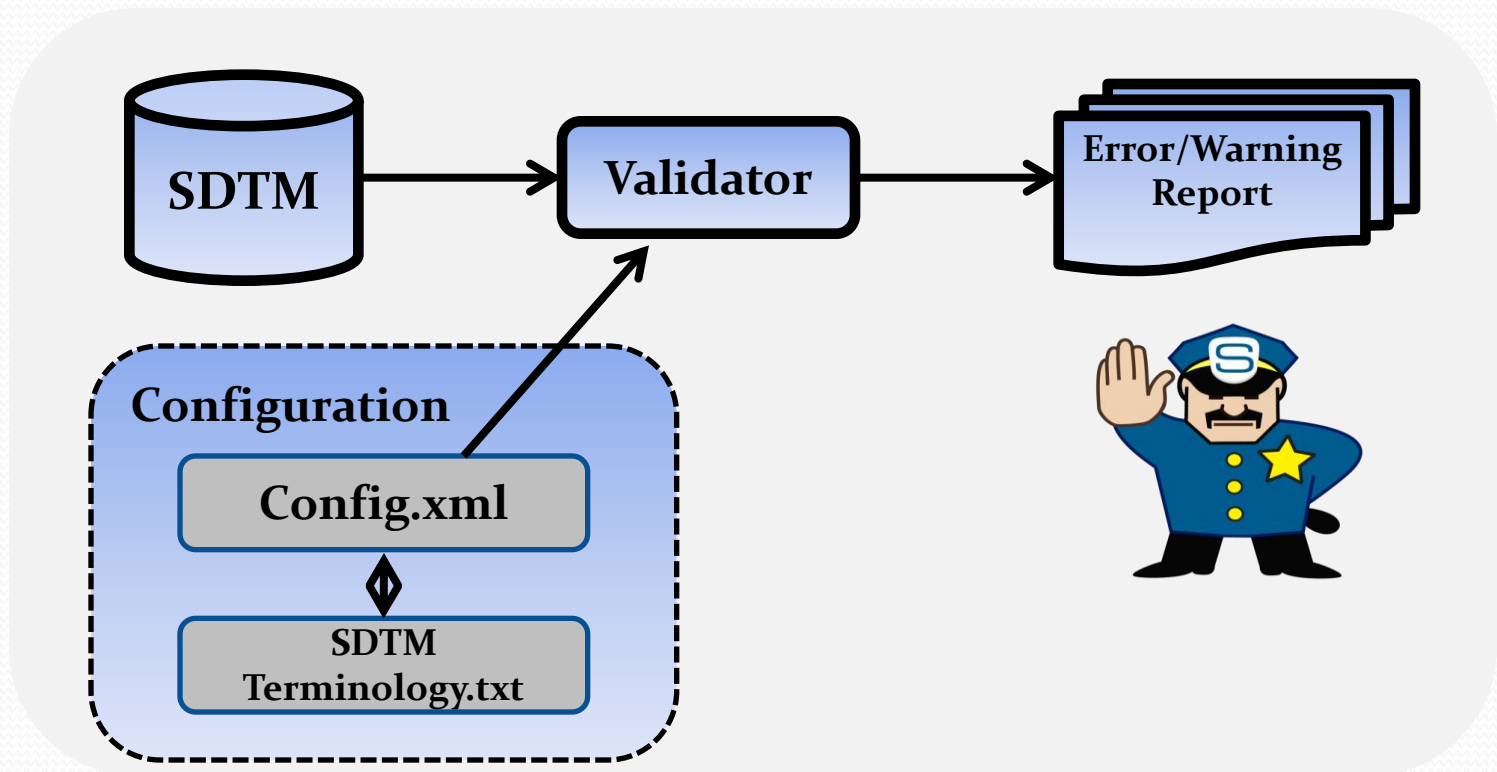
Rule ID	Message	Description of Rule	Domain	Type	Severity	References
IR4000	No rows in domain table	Identifies domain table that has zero rows and therefore contains no data.	All	Warning	Medium	
IR4001	Null value in column	Identifies a null (empty) value found in a column where (Standard) Core attribute is 'Req'	All	Error	High	SDTMIG 4.1.1.5
IR4002	Invalid ISO 8601 value	Identifies records where the value for a date doesn't conform to the ISO 8601 standard.	All	Error	High	SDTMIG 4.1.4.1
IR4003	Inconsistent value for DOMAIN	Identifies records where the value in the Domain Abbreviation column doesn't match the name of Domain	All	Warning	Low	SDTMIG 2.2 SDTMIG 10.3.1
IR4004	Non-unique value for SEQ	Identifies records where non-unique values for Sequence Number variable exist within a subject	All	Error	High	

Validation Rule Details

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- Left Sidebar:** A green box with a star icon and the text "MAX" contains a list of user actions: "My account", "Create content", "Administer", and "Log out". Below it, another green box titled "SUPPORTED CDISC STANDARDS" lists: "SDTM 3.1.1", "SDTM 3.1.2 (Beta 2)", "ADaM 1.0 (Beta 2)", "ODM 1.2.1 (Beta 2)", and "Define.xml 1.0 (Beta 2)".
- Center Content:** Features a "VIEW EDIT" header, the rule ID "IR4003", and a "Message: Inconsistent value for DOMAIN". The "Description of Rule" states: "Identifies records where the value in the Domain Abbreviation column doesn't match the name of Domain". Additional details include "Domain: All", "Type: Warning", and "Severity: Low". A "Delete post" link is present. Below this is a table titled "APPLIES TO" with columns for "Standard" and "References".
- Right Table:** A table with two columns: "Standard" and "References". It lists "SDTM 3.1.1" under the Standard column and "SDTMIG 2.2" and "SDTMIG 10.3.1" under the References column.
- Bottom Section:** A green bar labeled "COMMENTS" with a "POST NEW COMMENT" button below it.

Validator Architecture (SDTM)



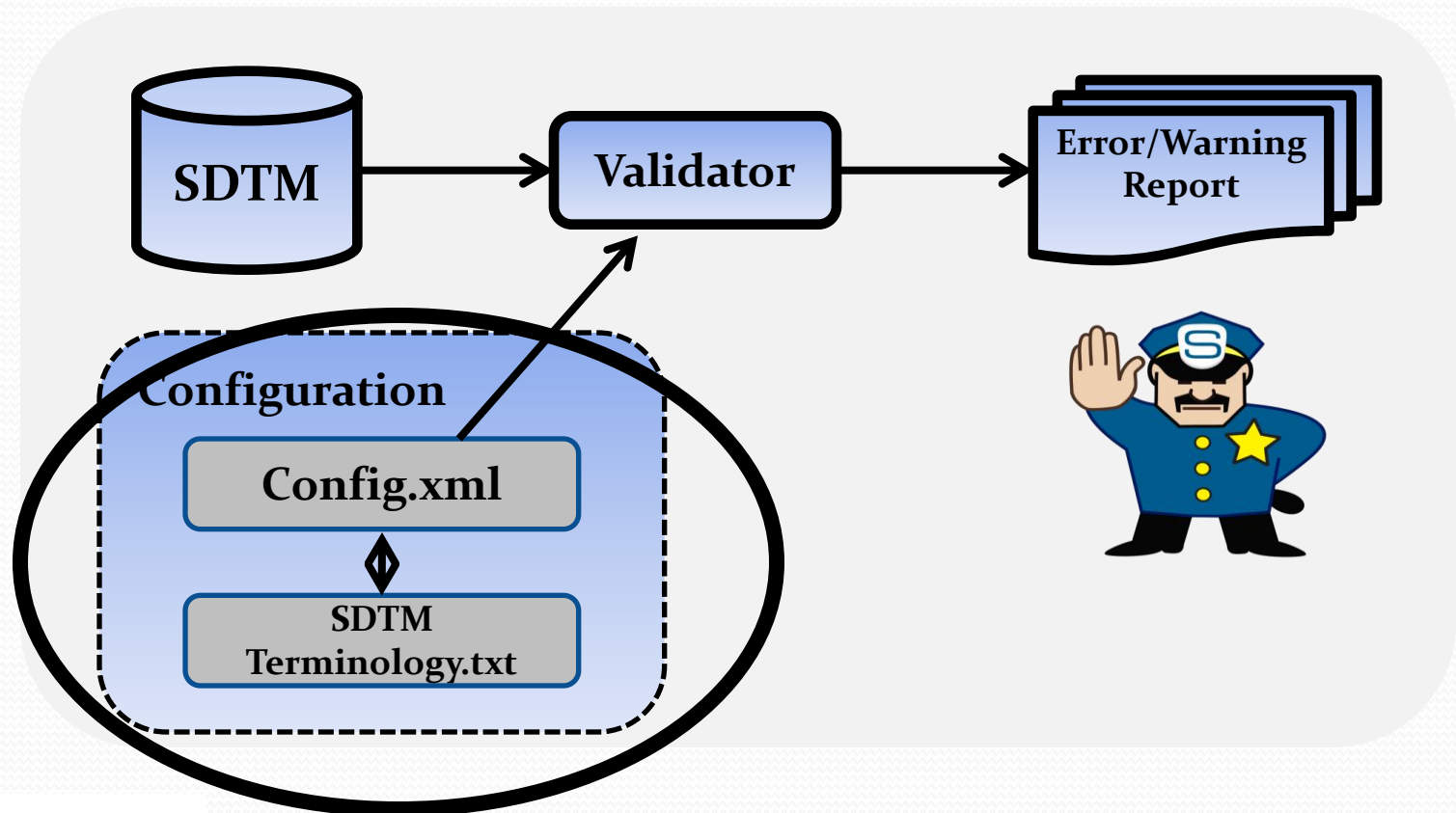
Supported Input

- SAS XPORT
- Delimited Text
- XML (Beta 2)

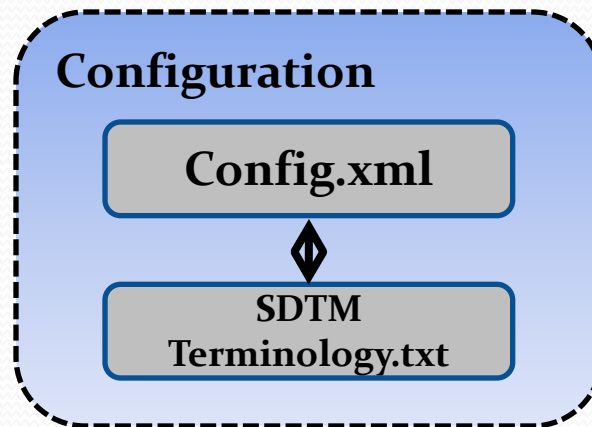
Validation Report

- XML
- Excel
- CSV
- HTML

Validator Architecture (SDTM)



Configuration



Home Insert Page Layout Formulas Data Review View Add-Ins

Cut Copy Paste Format Clipboard

Wrap Text Merge & Center Alignment

General Number

SDTM Terminology.txt

	A	B	C	D	E	
	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym
1	C66767		No	Action Taken with Study Treatment	ACN	Act
2	C49503	C66767		Action Taken with Study Treatment	DOSE INCREASED	
3	C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED	
4	C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED	
5	C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED	
6	C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN	
7	C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA
8	C17998	C66767		Action Taken with Study Treatment	UNKNOWN	U; U
9	C66768		No	Outcome of Event	OUT	Out
10	C48275	C66768		Outcome of Event	FATAL	Gra
11	C49494	C66768		Outcome of Event	NOT RECOVERED/NOT RESO	
12	C49498	C66768		Outcome of Event	RECOVERED/RESOLVED	
13	C49495	C66768		Outcome of Event	RECOVERED/RESOLVED WIT	
14	C49496	C66768		Outcome of Event	RECOVERING/RESOLVING	
15	C17998	C66768		Outcome of Event	UNKNOWN	U; U
16	C66780		Yes	Age Span	AGESPAN	Age
17	C27954	C66780		Age Span	ADOLESCENT (12-17 YEARS)	
18	C49685	C66780		Age Span	ADULT (18-65)	
19	C49683	C66780		Age Span	CHILDREN (2-11 YEARS)	
20	C16268	C66780		Age Span	ELDERLY (> 65)	

SDTM Terminology.txt



- Study Data Tabulation Model
- Operational Data Model
- Define.XML
- Study/Trial Design Model
- LAB
- ADaM
- Protocol
- Terminology**
- CDASH
- SEND
- CDISC SHARE
- Therapeutic Area Standards



Configuration

config-sdtm-3.1.2.xml - WordPad

File Edit View Insert Format Help



```

<val:ValidationRuleRef RuleID="SD1011" Active="Yes"/>
<val:ValidationRuleRef RuleID="SD1014" Active="Yes"/>
<val:ValidationRuleRef RuleID="SD1015" Active="Yes"/>
<!-- CDISC Controlled Terminology Rules -->
<val:ValidationRuleRef RuleID="CT0009" Active="Yes"/>
<val:ValidationRuleRef RuleID="CT0038" Active="Yes"/>
<val:ValidationRuleRef RuleID="CT0039" Active="Yes"/>
<val:ValidationRuleRef RuleID="CT0056" Active="Yes"/>
<val:ValidationRuleRef RuleID="CT0057" Active="Yes"/>
</ItemGroupDef>
<ItemGroupDef OID="SV" Name="SV" Repeating="Yes" IsReferenceData="No" Purpose="Tabulation" def:Label="Subject Visits" def:Structure=
<!-- ***** -->
<!-- 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="SV.SVSEQ" OrderNumber="4" Mandatory="No" Role="Identifier" val:Core="Permissible"/>
<ItemRef ItemOID="SV.SVGRPID" OrderNumber="5" Mandatory="No" Role="Identifier" val:Core="Permissible"/>
<ItemRef ItemOID="SV.SVREFID" OrderNumber="6" Mandatory="No" Role="Identifier" val:Core="Permissible"/>
<ItemRef ItemOID="SV.SVSPID" OrderNumber="7" Mandatory="No" Role="Identifier" val:Core="Permissible"/>
<ItemRef ItemOID="SV.VISITNUM" OrderNumber="8" Mandatory="Yes" Role="Topic" val:Core="Required"/>
<ItemRef ItemOID="SV.VISIT" OrderNumber="9" Mandatory="No" Role="Synonym Qualifier" val:Core="Permissible"/>
<ItemRef ItemOID="SV.VISITDY" OrderNumber="10" Mandatory="No" Role="Timing" val:Core="Permissible"/>
<ItemRef ItemOID="SV.SVSTDTCT" OrderNumber="11" Mandatory="No" Role="Timing" val:Core="Expected"/>

```

Define.xml
structure

Configuration

config-sdtm-3.1.2.xml - WordPad

File Edit View Insert Format Help



```

<val:ValidationRuleRef RuleID="SD1011" Active="Yes"/>
<val:ValidationRuleRef RuleID="SD1014" Active="Yes"/>
<val:ValidationRuleRef RuleID="SD1015" Active="Yes"/>
<!-- CDISC Controlled Terminology Rules -->
<val:ValidationRuleRef RuleID="CT0009" Active="Yes"/>
<val:ValidationRuleRef RuleID="CT0038" Active="Yes"/>
<val:ValidationRuleRef RuleID="CT0039" Active="Yes"/>
<val:ValidationRuleRef RuleID="CT0056" Active="Yes"/>
<val:ValidationRuleRef RuleID="CT0057" Active="Yes"/>
</ItemGroupDef>
<ItemGroupDef OID="SV" Name="SV" Repeating="Yes" IsReferenceData="No" Purpose="Tabulation" def:Label="Subject Visits" def:Structure=
<!-- ***** -->
<!-- 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="SV.SVSEQ" OrderNumber="4" Mandatory="No" Role="Identifier" val:Core="Permissible"/>
<ItemRef ItemOID="SV.SVGRPID" OrderNumber="5" Mandatory="No" Role="Identifier" val:Core="Permissible"/>
<ItemRef ItemOID="SV.SVREFID" OrderNumber="6" Mandatory="No" Role="Identifier" val:Core="Permissible"/>
<ItemRef ItemOID="SV.SVSPID" OrderNumber="7" Mandatory="No" Role="Identifier" val:Core="Permissible"/>
<ItemRef ItemOID="SV.VISITNUM" OrderNumber="8" Mandatory="Yes" Role="Topic" val:Core="Required"/>
<ItemRef ItemOID="SV.VISIT" OrderNumber="9" Mandatory="No" Role="Synonym Qualifier" val:Core="Permissible"/>
<ItemRef ItemOID="SV.VISITDY" OrderNumber="10" Mandatory="No" Role="Timing" val:Core="Permissible"/>
<ItemRef ItemOID="SV.SVSTDTCT" OrderNumber="11" Mandatory="No" Role="Timing" val:Core="Expected"/>

```

Activate/
Deactivate
Validation

Configuration

config-sdtm-3.1.2.xml - WordPad

File Edit View Insert Format Help



```

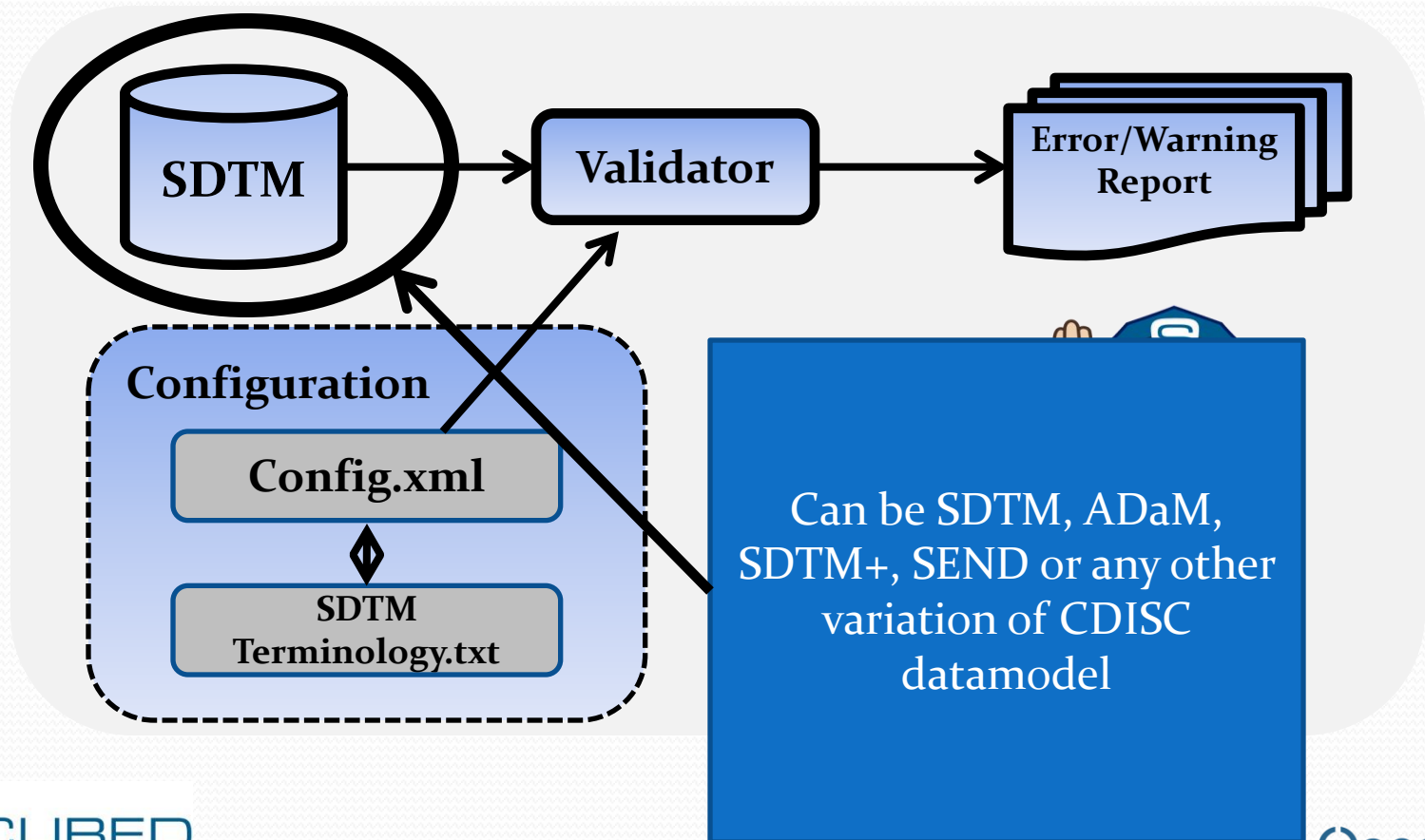
<!-- ***** -->
<!-- Prototype Definition section -->
<!-- ***** -->
<val:Prototype ItemGroupOID="EVENTS" KeyVariables="__TERM"/>
<val:Prototype ItemGroupOID="FINDINGS" KeyVariables="__TESTCD"/>
<val:Prototype ItemGroupOID="INTERVENTIONS" KeyVariables="__TRT"/>
<val:Prototype ItemGroupOID="SUPPQUAL" KeyVariables="QNAM"/>
<!-- ***** -->
<!-- Validation Rules section -->
<!-- ***** -->
<val:ValidationRules>
  <!-- ***** -->
  <!-- Janus Validation Rules -->
  <!-- ***** -->
  <val:Required ID="SD0002" Variable="%Variables.Core:Required%" Message="Null value in vari
  <val:Regex ID="SD0003" Variable="%Variables.Type:DateTime|Date|Time%" Test="%Variable.Type.
  <val:Match ID="SD0004" Variable="DOMAIN" Terms="%Domain%" Delimiter="," Message="Inconsiste
  <val:Unique ID="SD0005" Variable="%Domain%SEQ" GroupBy="USUBJID" When="%Domain%SEQ != ' ' " M
  <val:Lookup ID="SD0006" Variable="USUBJID == USUBJID" From="%Domains[EG, LB, QS, VS]%" Where="
  <val:Unique ID="SD0007" Variable="%Domain%STRESU" GroupBy="%Domain%TESTCD, %Domain%CAT" Matc
  <val:Condition ID="SD0009" Test="AESCAN == 'Y' @or AESCONG == 'Y' @or AESDISAB == 'Y' @or A
  <val:Regex ID="SD0010" Variable="VISITNUM" Test="\-?[0-9]+(\.[0-9]{1,3})?" Message="VISITNU
  
```

Validation
Rules
Definitions

Validation Rule - example

```
<val:Lookup ID="CT0002" Variable="CDISCSubmissionValue == AESEV"  
From="FILE:TAB:%System.ConfigDirectory%/data/SDTM Terminology.txt"  
Where="CodelistCode == 'C66769'"  
When="AESEV != ''"  
  
Message="Value for AESEV not found in AESEV controlled terminology  
codelist"  
  
Description="Variable values should be populated with terms found in  
'Severity/Intensity Scale for Adverse Events' (C66769) CDISC controlled  
terminology codelist"  
  
Category="Terminology"  
  
Type="Warning"  
  
Severity="Medium"/>
```

Validator Architecture (SDTM)



How can you contribute?

- Individuals
 - Use the tools and provide feedback
 - Share your experience and provide requirements
 - Help with testing, development, or documentation
- Companies
 - Collaborate on development projects
 - Contribute code or resources

Questions/Feedback

Read paper or visit <http://www.opencdisc.org> for more details

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Founder and President OpenCdisc