

Using the
SAS® Clinical Standards Toolkit 1.4
to work with
the CDISC ODM model

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Agenda

- Introduction to the SAS® Clinical Standards Toolkit (CST)
- CDISC - Operational Data Model (ODM)
- SAS® Clinical Standards Toolkit and ODM
 - SAS Data Model for ODM
 - Generic CST process
 - Reading and Writing ODM
 - Validating ODM
 - Clinical Data in ODM



What is the SAS Clinical Standards Toolkit (CST)?

What is the SAS Clinical Standards Toolkit?

- **Framework** to primarily support **Clinical Research** activities.
- Initially focusing on standards as defined by CDISC, but not limited to CDISC.
- Designed as an integral part of **Clinical Data Integration** (CDI), but is available to all SAS users as open source SAS Macros and metadata.
- Designed to supersede PROC CDISC
- **Framework**: designed to **customize** and **extend**

What is the SAS Clinical Standards Toolkit?

- A collection of metadata and "tools", providing an initial set of standards and functionality that is evolving and growing with updates and releases.
- Provides SAS representation of published standards as SAS data sets and catalogs
 - Contents standards: SDTM, ADaM
 - XML standards: Define-XML and ODM
 - Controlled Terminology

What is the SAS Clinical Standards Toolkit?

Supported CDISC standards in Toolkit 1.4:

- **SDTM** 1.3.1 and 3.1.2
- **ADaM** 2.1 1 (ADSL, Basic Data Structure and Analysis Results Metadata templates; v1.1 of the ADaM validation checks)
- **CRT-DDS** 1.0 (define.xml – Create / Import / Validate)
- **ODM** 1.3.0 - Read / Write / Validate
- **NCI CDISC Controlled Terminology** (April 2011)

SAS Clinical Standards Toolkit 1.4 (Q4 2011)

- Supported with SAS 9.3 on the following operating systems:
 - Windows 32
 - Windows for x64
 - Linux for x64
 - Solaris SPARC
 - Solaris AMD
 - HP-UX Itanium
- Separately orderable component
- Available at no additional charge to currently licensed SAS customers.
- Contact your SAS Account Representative concerning availability.



Operational Data Model ODM

Operational Data Model (ODM)

- XML standard published by CDISC
- Support data interchange and archive
- Represent an entire clinical study
 - Study metadata, administrative metadata, reference data, subject data
- Comply with 21 CFR Part 11 (and associated regulatory requirements)
- Designed to be compatible with clinical data applications
- Platform and Vendor neutral

Operational Data Model (ODM)



ODM Version 1.3.1

ODM version 1.3.1 is available here

You can download the standard as separate elements:

- ODM 1.3.1.xsd
- ODM 1.3.1 Final.html
- ODM 1.3.1 Foundation.xsd
- Read Me.txt
- xlink.xsd
- xml.xsd
- xmldsig core schema.xsd

Operational Data Model (ODM)



ODM Version 1

ODM version 1.3.1 is available

You can download the standard

- ODM 1.3.1.xsd
- ODM 1.3.1 Final.html
- ODM 1.3.1 Foundation
- Read Me.txt
- xlink.xsd
- xml.xsd
- xmldsig core schema.



Clinical Data Interchange Standards Consortium

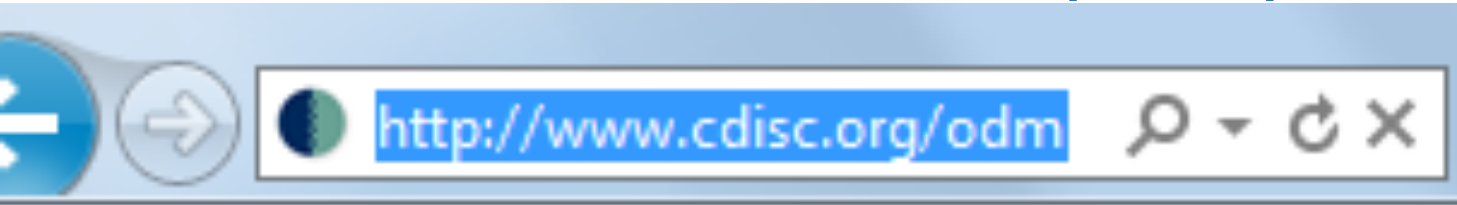
Specification for the Operational Data Model (ODM)

Version 1.3.1 Production
Source File: ODM1-3-1.htm
Last Update: 2010-02-11

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An official copy of this document is available on the ODM page of the CDISC website <http://www.cdisc.org/odm>.

Operational Data Model (ODM)



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- ODM 1.3.1.xsd
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- ODM 1.3.1 Foundation.xsd
- Read Me.txt
- xlink.xsd
- xml.xsd
- xmldsig core schema.xsd



ODM1-3-1.xsd

Type: XML Schema



ODM1-3-1-foundation.xsd

Type: XML Schema



xlink.xsd

Type: XML Schema



xml.xsd

Type: XML Schema



xmldsig-core-schema.xsd

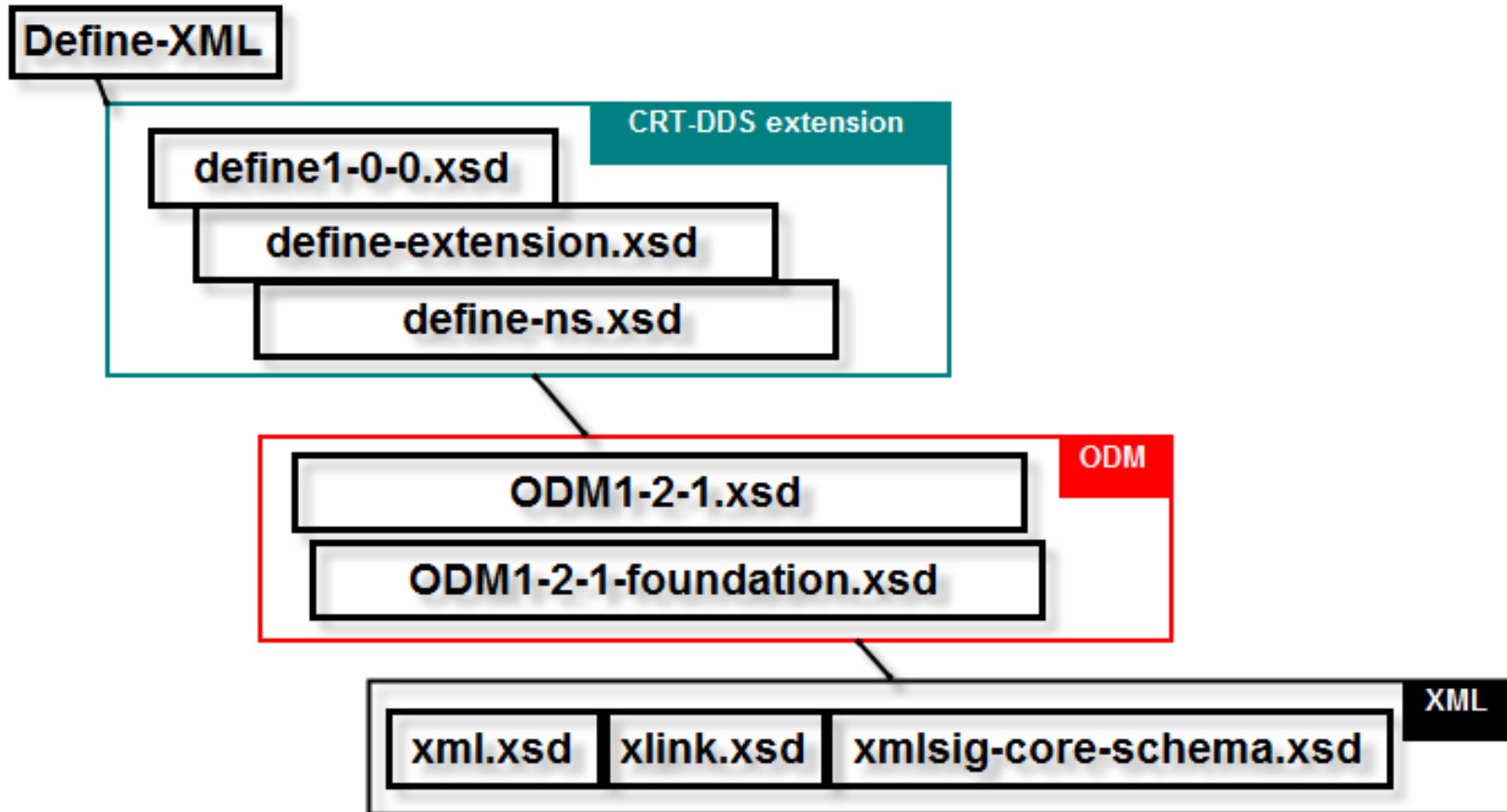
Type: XML Schema

Operational Data Model (ODM)

- Extensible by design
- Foundation for other CDISC production standards:
 - Define-XML (CRT-DDS , define.xml)
 - SDM-XML (Study Design Model)
 - ODM-CT-XML (Controlled Terminology in ODM)
- (to follow: CDASH-ODM, xxx-ODM)

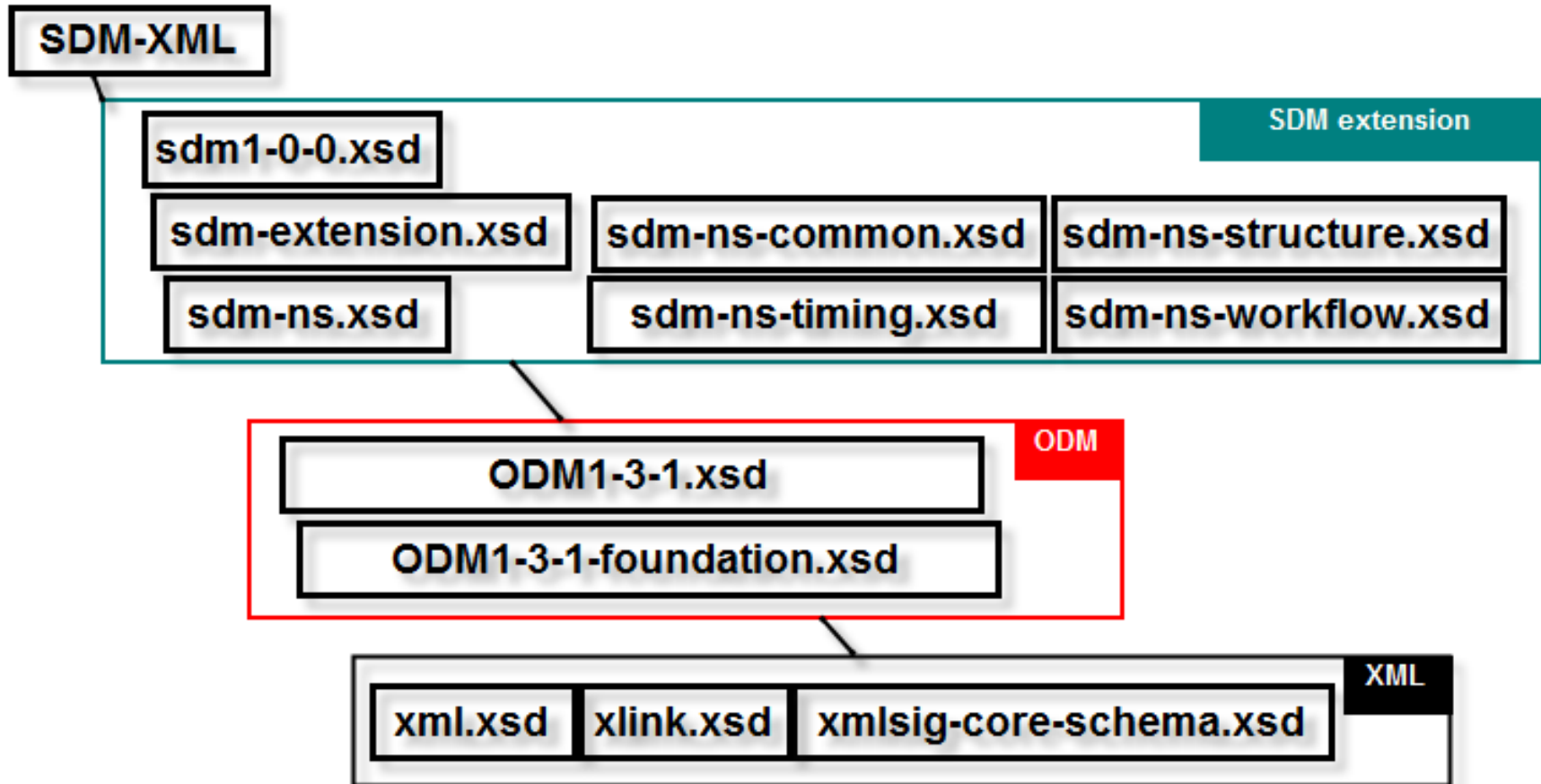
Operational Data Model (ODM)

- Foundation for Define-XML



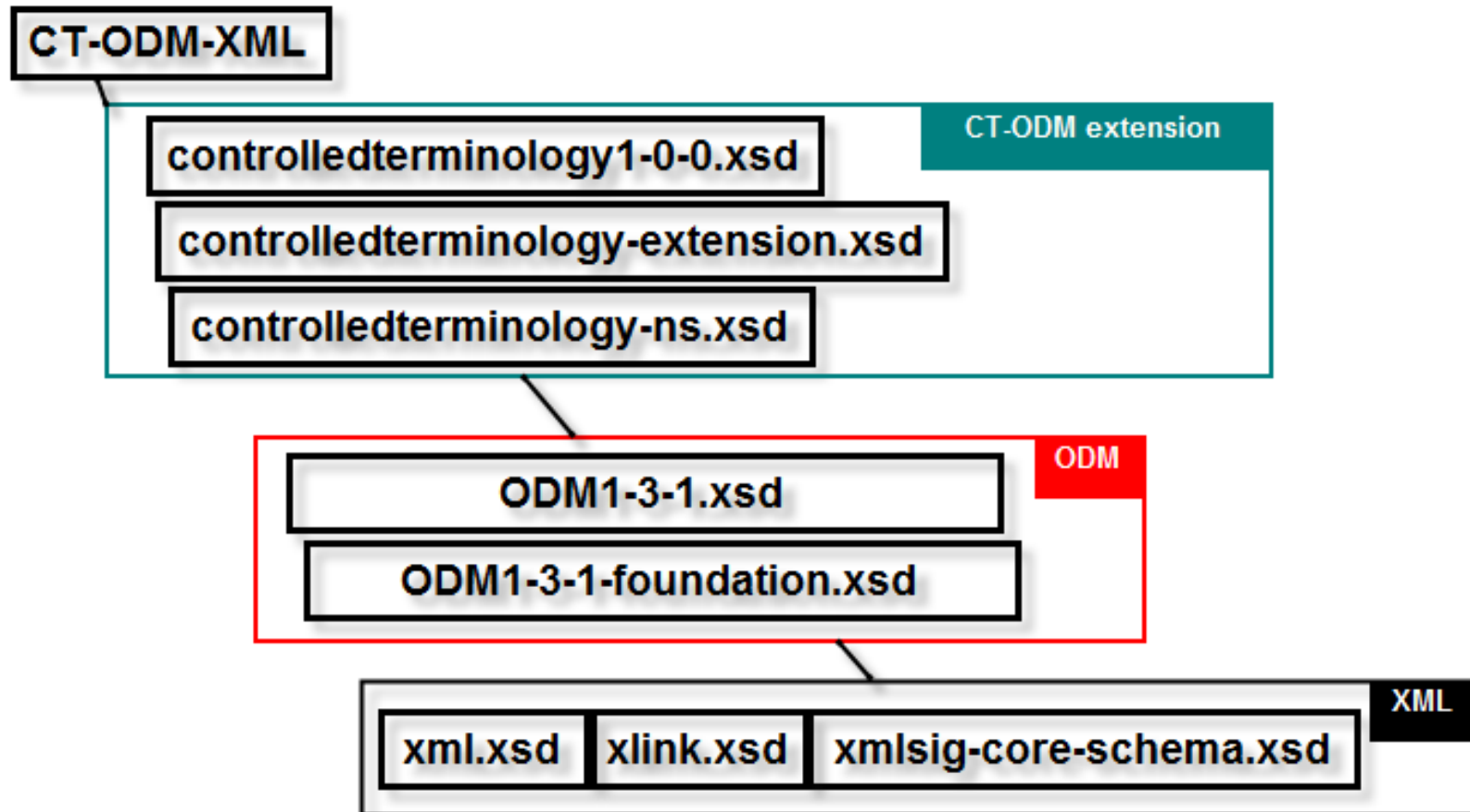
Operational Data Model (ODM)

- Foundation for SDM-XML (Study Design Model)



Operational Data Model (ODM)

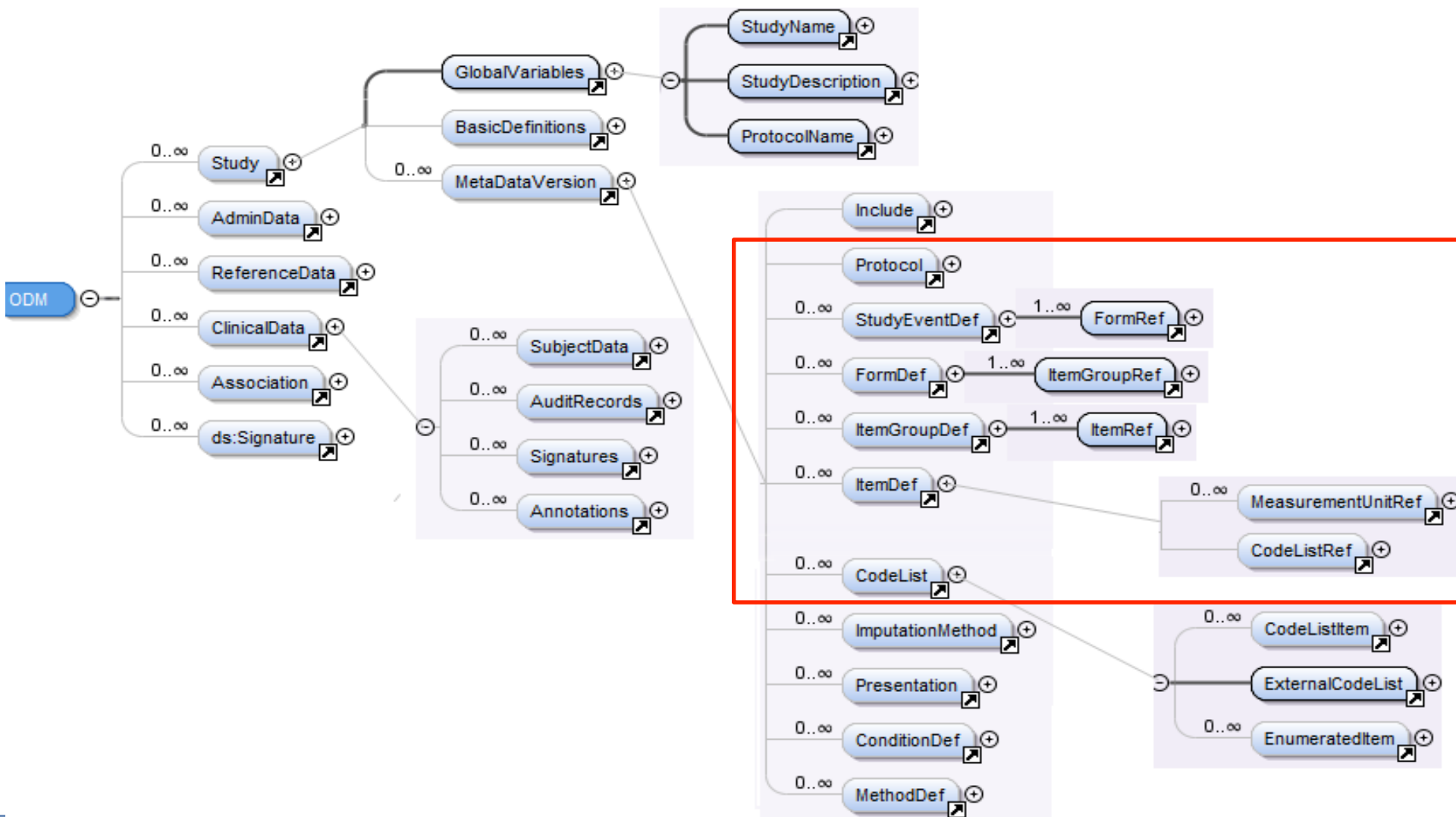
- Foundation for ODM-CT-XML



SAS Data Model for ODM

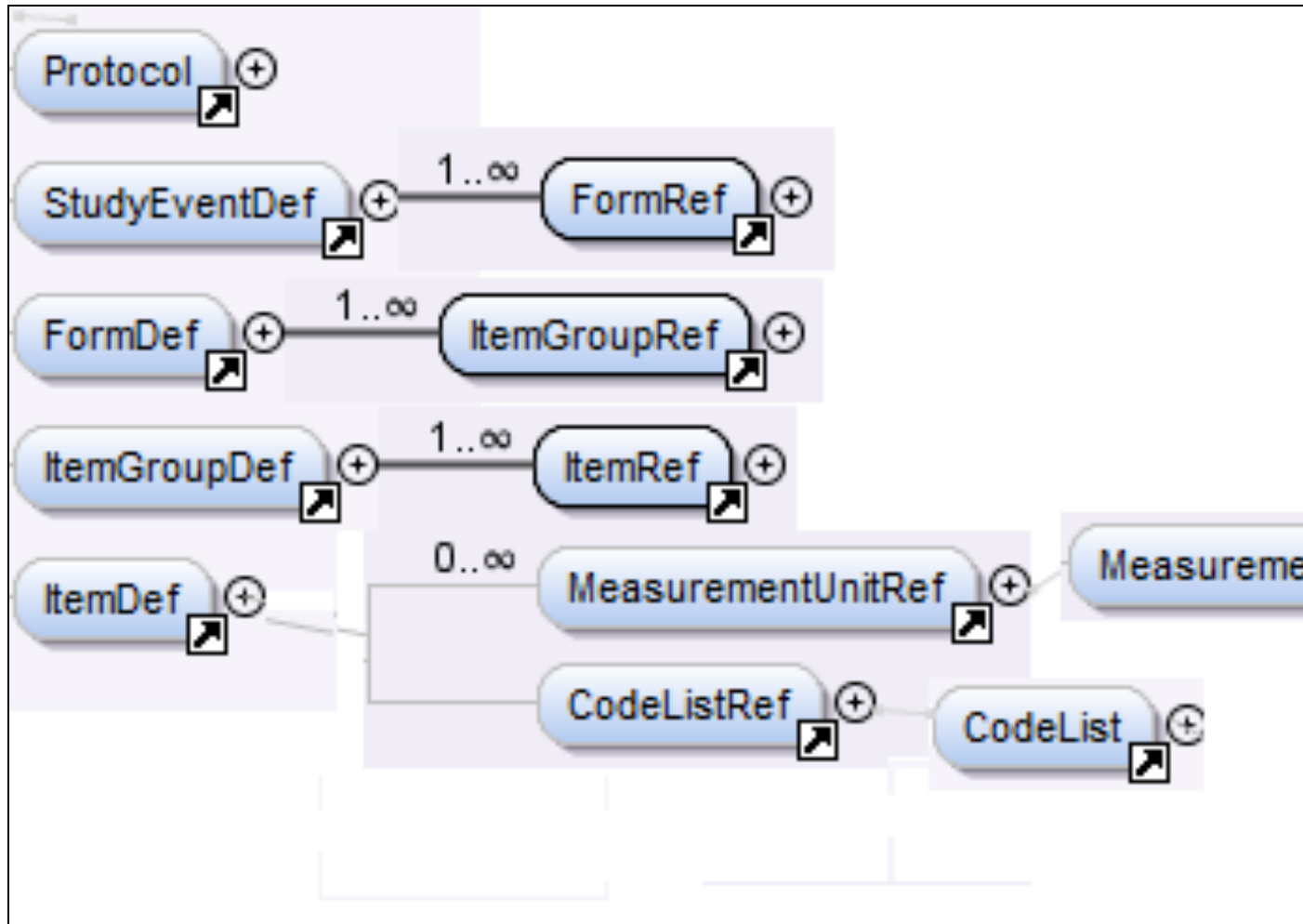
SAS Data Model for ODM

- ODM in XML has a deep hierarchy and many relations



SAS Data Model for ODM

- ODM in XML has a deep hierarchy and many relations



SAS Data Model for ODM

```
<Protocol>
  <Description>
    <TranslatedText xml:lang="en">Protocol description</TranslatedText>
    <TranslatedText xml:lang="fr-CA">Description du protocole</TranslatedText>
  </Description>
  <StudyEventRef Mandatory="Yes" OrderNumber="1" StudyEventOID="StudyEventDefs.OID1.Screening"/>
</Protocol>

<StudyEventDef OID="StudyEventDefs.OID1.Screening" Category="Screening"
  Name="Screening" Repeating="No" Type="Scheduled">
  <FormRef FormOID="FormDefs.MH" Mandatory="Yes" OrderNumber="1"/>
</StudyEventDef>

<FormDef OID="FormDefs.MH" Name="Medical History" Repeating="No">
  <ItemGroupRef ItemGroupOID="ItemGroupDefs.mh.ids" Mandatory="Yes" OrderNumber="0"/>
  <ItemGroupRef ItemGroupOID="ItemGroupDefs.mh.events" Mandatory="Yes" OrderNumber="1"/>
</FormDef>

<ItemGroupDef OID="ItemGroupDefs.OID.mh.events" Name="Medical History Event Columns" Repeating="Yes"
  IsReferenceData="No" SASDatasetName="mh_evnt" Domain="MH" Purpose="Tabulation">
  <ItemRef ItemOID="ItemDef.OID.MH.MHSTAT" Mandatory="No" OrderNumber="15" Role="RecordQualifier"/>
  <ItemRef ItemOID="ItemDef.OID.MH.MHREASND" Mandatory="No" OrderNumber="16" Role="RecordQualifier"/>
</ItemGroupDef>

<ItemDef OID="ItemDef.OID.MH.MHSTAT" Name="MHSTAT" DataType="string" Length="40" SASFieldName="MHSTAT"
  Comment="The status indicates that the pre-specified question was not answered.">
  <CodeListRef CodeListOID="CodeLists.OID.ND"/>
</ItemDef>

<CodeList OID="CodeLists.OID.ND" Name="ND" DataType="text" SASFormatName="$ND" >
  <CodeListItem CodedValue="ND">
    <Decode>
      <TranslatedText xml:lang="en">NOT DONE</TranslatedText>
      <TranslatedText xml:lang="sw">SI KUFANYIKA</TranslatedText>
      <TranslatedText xml:lang="si">නොවී දෙන්න</TranslatedText>
    </Decode>
  </CodeListItem>
</CodeList>
```

SAS Data Model for ODM

```
<FormDef OID="FormDefs.MH" Name="Medical History" Repeating="No"
  <ItemGroupRef ItemGroupOID="ItemGroupDefs.mh.ids" Mandatory="Yes"
  <ItemGroupRef ItemGroupOID="ItemGroupDefs.mh.events" Mandatory="Yes"
</FormDef>
```

```
<ItemGroupDef OID="ItemGroupDefs.OID.mh.events" Name="Medical History Events"
  IsReferenceData="No" SASDatasetName="mh_evnt" Domain="Medical History"
  <ItemRef ItemOID="ItemDef.OID.MH.MHSTAT" Mandatory="No" Order="1"
  <ItemRef ItemOID="ItemDef.OID.MH.MHREASND" Mandatory="No" Order="2"
</ItemGroupDef>
```

නොවී දෙනේ

SAS Data Model for ODM

- SAS Clinical Standards Toolkit v1.4 provides data model that represents the ODM Version 1.3.0 format in 66 SAS data sets
- Patterned to match the XML element and attribute structure of the ODM XML format
- XML element → table, XML attribute → column

SAS Data Model for ODM

```
<ItemGroupDef OID="ItemGroupDefs.OID.DM" Name="DM" Repeating="No"
  IsReferenceData="No" SASDatasetName="DM" Domain="DM" Purpose="Tabulation">
```

```
<ItemRef ItemOID="ItemDef.OID.DM.STUDYID" Mandatory="Yes" OrderNumber="1" KeySequence="1" Role="Identifier"/>
<ItemRef ItemOID="ItemDef.OID.DM.DOMAIN" Mandatory="Yes" OrderNumber="2" Role="Identifier"/>
<ItemRef ItemOID="ItemDef.OID.DM.USUBJID" Mandatory="Yes" OrderNumber="3" KeySequence="2" Role="Identifier"/>
<ItemRef ItemOID="ItemDef.OID.DM.SITR.ITD" Mandatory="Yes" OrderNumber="4" Role="Timing"/>
```

...

```
<ItemRef ItemOID="ItemDef.OID.DM.DMDTC" Mandatory="No" OrderNumber="19" Role="Timing"/>
<ItemRef ItemOID="ItemDef.OID.DM.DMDY" Mandatory="No" OrderNumber="20" Role="Timing"/>
```

```
</ItemGroupDef>
```

```
<ItemDef OID="ItemDef.OID.DM.DMDTC" Name="DMDTC" DataType="string" Length="64" SASFieldName="DMDTC"
  Comment="Date/time of demographic data collection."/>
<ItemDef OID="ItemDef.OID.DM.DMDY" Name="DMDY" DataType="integer" Length="8" SASFieldName="DMDY"
  Comment="Study day of collection measured as integer days."/>
```

SAS Data Model for ODM

VIEWTABLE: Srcdata.Itemgroupdefs

OID	Name	Repeating	IsReferenceData	SASDatasetName	Domain
ItemGroupDefs.OID.DM	DM	No	No	DM	DM
ItemGroupDefs.OID.AE	Adverse Events	Yes		AE	AE
ItemGroupDefs.OID.LB	LB	Yes	No	LB	LB
ItemGroupDefs.OID.labnormalran	Lab normal ranges	No	Yes	labnorm	
ItemGroupDefs.OID.mh.events	Medical History Event Columns	Yes	No	mh_evt	MH
ItemGroupDefs.OID.mh.ids	Medical History Identifier Columns	No	No	mh_id	MH
ItemGroupDefs.OID.mh.dates	Medical History Timing Columns	Yes	No	mh_dat	MH
ItemGroupDefs.OID.VS	VS	Yes	No	VS	VS

VIEWTABLE: Srcdata.Itemgroupdefitemrefs

ItemOID	Mandatory	OrderNumber	KeySequence	MethodOID	Role	FK_ItemGroupDefs
ItemDef.OID.DM.STUDYID	Yes	1	1		Identifier	ItemGroupDefs.OID.DM
ItemDef.OID.DM.DOMAIN	Yes	2	.		Identifier	ItemGroupDefs.OID.DM
ItemDef.OID.DM.USUBJID	Yes	3	2		Identifier	ItemGroupDefs.OID.DM
ItemDef.OID.DM.DMDTC	No	19	.		Timing	ItemGroupDefs.OID.DM
ItemDef.OID.DM.DMDY	No	20	.		Timing	ItemGroupDefs.OID.DM

VIEWTABLE: Srcdata.Itemdefs

OID	Name	Data Type	Length	SignificantD	SASFieldName	Origin	Comment	CodeListRef
ItemDef.OID.DM.COUNTRY	COUNTRY	string	3	.	COUNTRY		Country of the investigational site in which the subject participated in the trial.	CodeLists.OID.COUNTRY
ItemDef.OID.DM.DMDTC	DMDTC	string	64	.	DMDTC		Date/time of demographic data collection.	
ItemDef.OID.DM.DMDY	DMDY	integer	8	.	DMDY		Study day of collection measured as integer days.	

SAS Data Model for ODM

 admindata.sas7bdat	 annotation.sas7bdat	 annotationflag.sas7bdat
 association.sas7bdat	 auditrecord.sas7bdat	 clinicaldata.sas7bdat
 clitemdecodetranslatedtext.sas7b...	 codelistitems.sas7bdat	 codelists.sas7bdat
 conditionefformalexpression.sas...	 conditiondefs.sas7bdat	 conditiondeftranslatedtext.sas7bd...
 enumerateditems.sas7bdat	 externalcodelists.sas7bdat	 formdata.sas7bdat
 formdefarchlayouts.sas7bdat	 formdefitemgrouprefs.sas7bdat	 formdefs.sas7bdat
 formdeftranslatedtext.sas7bdat	 imputationmethods.sas7bdat	 itemaliases.sas7bdat
 itemdata.sas7bdat	 itemdefs.sas7bdat	 itemdeftranslatedtext.sas7bdat
 itemgroupaliases.sas7bdat	 itemgroupdata.sas7bdat	 itemgroupdefitemrefs.sas7bdat
 itemgroupdefs.sas7bdat	 itemgroupdeftranslatedtext.sas7b...	 itemmurefs.sas7bdat
 itemquestionexternal.sas7bdat	 itemquestiontranslatedtext.sas7b...	 itemmrcformalexpression.sas7bdat
 itemrangechecks.sas7bdat	 itemrangecheckvalues.sas7bdat	 itemrole.sas7bdat
 keyset.sas7bdat	 location.sas7bdat	 locationversion.sas7bdat
 measurementunits.sas7bdat	 metadataversion.sas7bdat	 methodefformalexpression.sas7...
 methoddefs.sas7bdat	 methoddeftranslatedtext.sas7bdat	 mutranslatedtext.sas7bdat
 odm.sas7bdat	 presentation.sas7bdat	 protocoleventrefs.sas7bdat
 protocoltranslatedtext.sas7bdat	 rcerrortranslatedtext.sas7bdat	 referencedata.sas7bdat
 signature.sas7bdat	 signaturedef.sas7bdat	 study.sas7bdat
 studyeventdata.sas7bdat	 studyeventdefs.sas7bdat	 studyeventdeftranslatedtext.sas7b...
 studyeventformrefs.sas7bdat	 subjectdata.sas7bdat	 user.sas7bdat
 useraddress.sas7bdat	 useraddressstreetname.sas7bdat	 useremail.sas7bdat
 userfax.sas7bdat	 userlocationref.sas7bdat	 userphone.sas7bdat

CST Framework

CST Framework

Consists of two distinct pieces (default installation):

- The components that are installed as part of SAS Foundation and shared files. (SAS Macros, Java JAR files, etc.)
 - » *SASROOT:\ClinicalStandardsToolkitFramework\...*
 - » *SASROOT:\SASClinicalStandardsToolkitCRTDDS10\...*
 - » *SASROOT:\SASClinicalStandardsToolkitODM130\...*
 - » *SASROOT:\SASFoundation\9.3\cstframework\sasmacro*
- The global standards library
 - » *C:\cstGlobalLibrary\...*

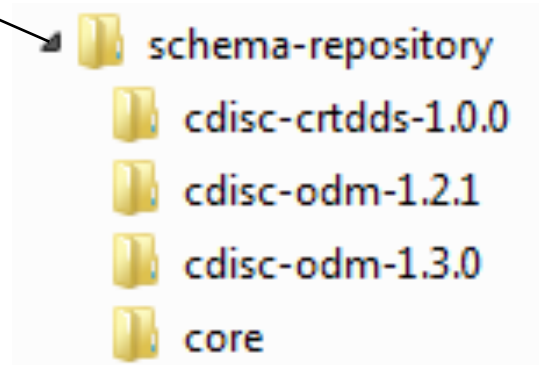
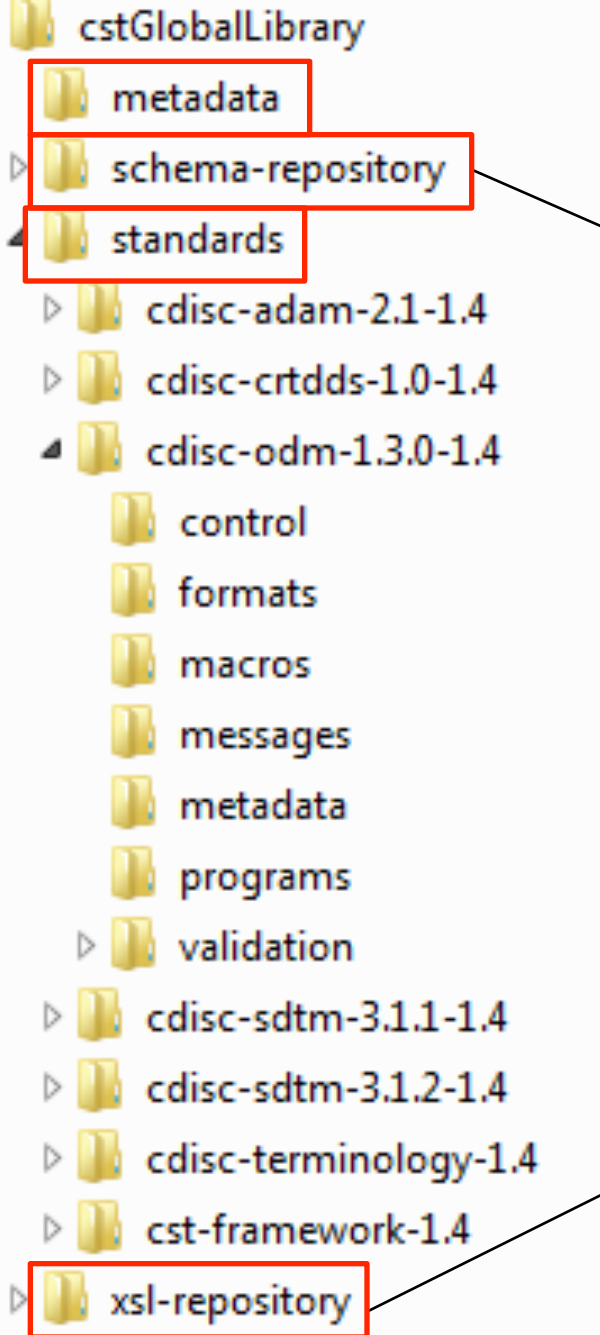
CST Framework

The Global Standards Library is created during installation. A series of directories are created here:

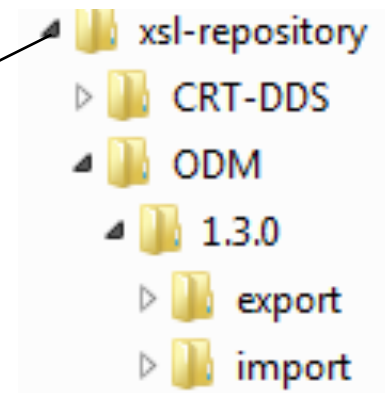
- **/metadata** : contains data sets that have information about the registered standard versions.
- **/schema-repository** : contains schemas for XML-based standards that are supported
- **/standards** : contains directories for each of the supported standards.
- **/xsl-repository** : contains directories and XSL files used in reading and writing XML files.

CST Framework

The Global Standards Library

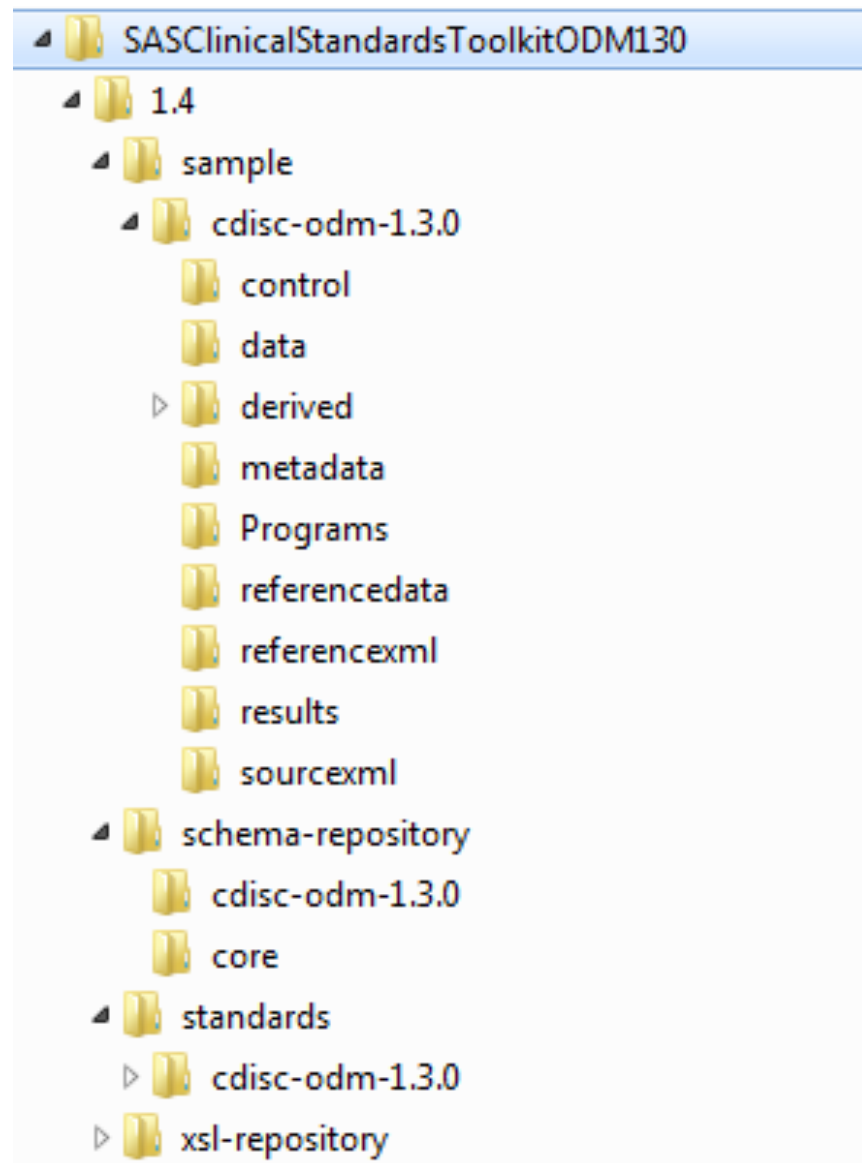
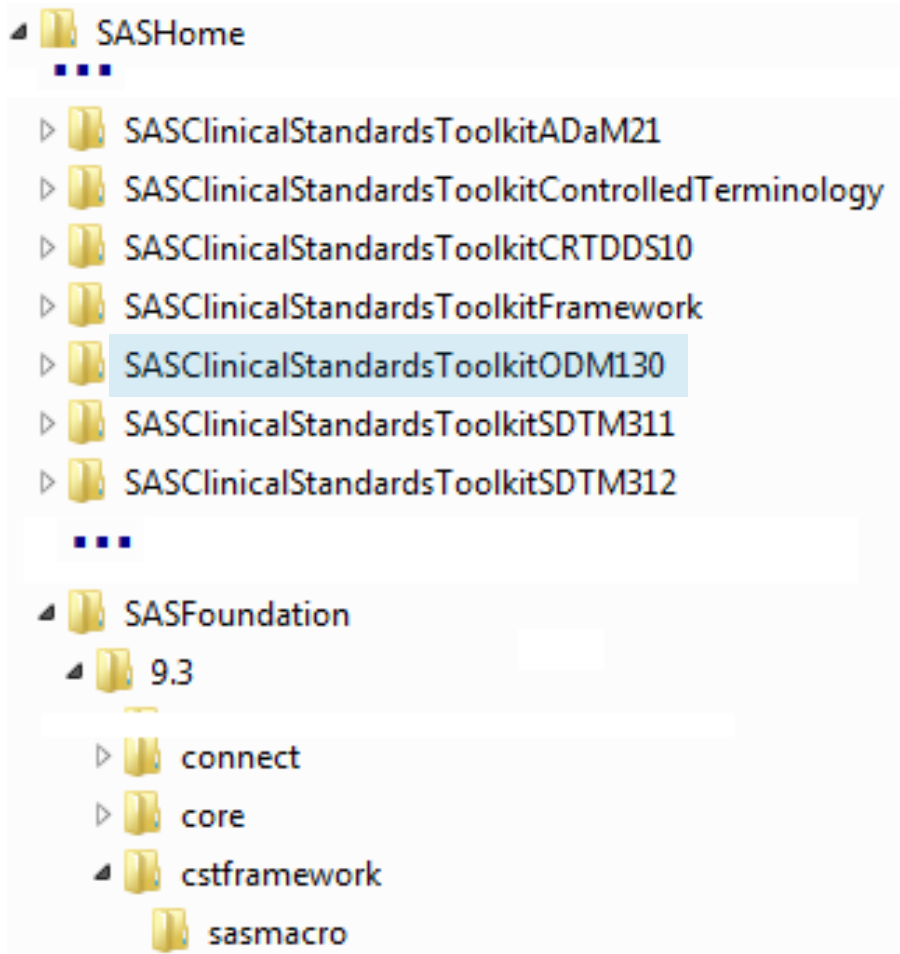


For XML



CST Framework

SASROOT (read-only ...)



CST Metadata Files

SAS Clinical Standards Toolkit Metadata

Toolkit provides and uses a series of metadata files to support basic core functions of the toolkit.

Standards	Validation_Master (Validation_Control)
StandardSASReferences	Reference_Tables (Source_Tables)
Standardlookup	Reference_Columns (Source_Columns)
SASReferences	Validation_Metrics
Properties	Validation_Results
Messages	

SAS Clinical Standards Toolkit Metadata

The **SASReferences** data set is the “brain center” of the Toolkit. Used to tell Toolkit where things are located. Can be created by the user or generated through the Toolkit. Many users will create their own SASReferences data set.

VIEWTABLE: Work.Sasreferences

standard	type	subtype	SASref	reftype	path	memname
CST-FRAMEWORK	messages		messages	libref		
CDISC-ODM	messages		odmmmsg	libref		
CDISC-ODM	autocall		odmcode	fileref		
CDISC-ODM	sourcedata		srcdata	libref	!sasroot/.../SASClinicalStandardsToolkitODM130/1.4/sample/cdisc-odm-1.3.0/derived/data	
CDISC-ODM	sourcemetadata	table	srcmeta	libref	!sasroot/.../SASClinicalStandardsToolkitODM130/1.4/sample/cdisc-odm-1.3.0/derived/metadata	source_tables.sas7bdat
CDISC-ODM	sourcemetadata	column	srcmeta	libref	!sasroot/.../SASClinicalStandardsToolkitODM130/1.4/sample/cdisc-odm-1.3.0/derived/metadata	source_columns.sas7bdat
CDISC-ODM	targetdata		trgdata	libref	!sasroot/.../SASClinicalStandardsToolkitODM130/1.4/sample/cdisc-odm-1.3.0/derived/formats	
CDISC-ODM	referencemetadata	table	refmeta	libref		
CDISC-ODM	referencemetadata	column	refmeta	libref		
CDISC-ODM	results	results	results	libref	!sasroot/.../SASClinicalStandardsToolkitODM130/1.4/sample/cdisc-odm-1.3.0/results	read_results.sas7bdat
CDISC-ODM	extenaxml	xml	odmxml	fileref	!sasroot/.../SASClinicalStandardsToolkitODM130/1.4/sample/cdisc-odm-1.3.0/sourcexml	odm_sample.xml
CDISC-ODM	referencexml	map	odmmmap	fileref	!sasroot/.../SASClinicalStandardsToolkitODM130/1.4/sample/cdisc-odm-1.3.0/referencexml	odm.map
CDISC-ODM	properties	initialize	inprop	fileref		initialize.properties

SAS Clinical Standards Toolkit Metadata

Property files (i.e. initialize.properties) set default preferences for each process. Properties are a series of name-value pairs that are translated into global macro variables available for the duration of a Toolkit process. Invoked by the ***cst_setProperties*** macro.

```
_cstDebug=0
_cstDebugOptions=mprint mlogic symbolgen mautoocdisplay
_cst_rc=0
_cst_MsgID=
_cst_MsgParm1=
_cst_MsgParm2=
_cstResultSeq=0
_cstSeqCnt=0
_cstSrcData=
_cstResultFlag=0
_cstResultsDS=work._cstresults
_cstMessages=work._cstmessages
_cstReallocateSASRefs=0
_cstFMTLibraries=work
_cstMessageOrder=APPEND
_cstSASRefsLoc=
_cstSASRefsName=
_cstSASRefs=work._cstsasrefs
```

SAS Clinical Standards Toolkit Metadata

Messages data sets are used to store information about the framework and standards validation checks. There are framework messages (CST prefix) and standards validation messages (e.g CRT prefix)

	 resultid	 standardversion	 checksource	 sourceid	 checkseverity
1	ODM0001	---	XMLTRANSFOR..	ODM0001	Info
2	ODM0002	---	XMLTRANSFOR..	ODM0002	Warning
3	ODM0003	---	XMLTRANSFOR..	ODM0003	Error
4	ODM0004	---	SAS	ODM0004	Error
5	ODM0005	---	SAS	ODM0005	Error
6	ODM0006	---	SAS	ODM0006	Error
7	ODM0007	---	SAS	ODM0007	Error

 sourcedescription	 messagetext	 parameter1
Message not received from XMLTransform	&_cstResultParm1	Message not retrieved from XMLTrans ..
Message not received from XMLTransform	&_cstResultParm1	Message not retrieved from XMLTrans ..
Message not received from XMLTransform	&_cstResultParm1	Message not retrieved from XMLTrans ..
	The following information..	Information Missing
	&_cstParam1 was not as...	
	The parameter &_cstPar...	
	The libname &_cstParam...	

SAS Clinical Standards Toolkit Metadata

Results data set. Each Toolkit process generates a results data set that can optionally be persisted beyond the SAS session based on SASReferences data set settings. Each results data set captures the outcome of specific process actions, using the *messages* data sets to standardize output.

VIEWTABLE: Results.Validation_results

resultid	seqno	srcdata	message	resultseverity	resultflag	_cst_rc
CST0100	1	SRCDATA.ITEMDATA (SRCDATA.SIGNATURE)	No errors detected in source data	Info	0	0
ODM0110	1	SRCDATA.ITEMDEFS (SRCDATA.CODELISTS)	The foreign key OID does not have a corresponding value in the target data set SRCDATA.ITEMDEFS	Error	1	0
CST0100	1	SRCDATA.ITEMDEFS (SRCDATA.METADATAVERS	No errors detected in source data	Info	0	0

VIEWTABLE: Results.Validation_results

resultflag	_cst_rc	actual	keyvalues
0	0		
1	0	CODELISTREF=CodeLists.OID.LBTEST	FK_METADATAAVERSION=MetaDataVersion.OID.1,OID=ItemDef.OID.LB.LBTEST
0	0		

SAS Clinical Standards Toolkit Metadata

Validation_Master & Validation_Control

Validation_master contains ALL standard specific validation information. **Validation_control** contains study specific validation information and is created from validation_master. The “brain center” of the Toolkit validation process.

	checkid	standard	standardversion	checksource	sourceid	checkseverity	checktype	codesource	usesourcemetac
1	ODM0100	CDISC-ODM	---	SAS	ODM0100	Error	Structural	cstcheck_notunique	Y
2	ODM0101	CDISC-ODM	---	SAS	ODM0101	Error	Content	cstcheck_violatesstd	Y
3	ODM0106	CDISC-ODM	---	SAS	ODM0106	Error	Content	cstcheck_column	Y
4	ODM0106	CDISC-ODM	---	SAS	ODM0106	Error	Content	cstcheck_column	Y
5	ODM0106	CDISC-ODM	---	SAS	ODM0106	Error	Content	cstcheck_column	Y
6	ODM0106	CDISC-ODM	---	SAS	ODM0106	Error	Content	cstcheck_column	Y

	tablescope	columnscope	code logic
1	_ALL_		
2	_ALL_		if (upcase(core&k)="REQ" and missing(&&_cstColArray&k)) the...
3	CLITEMDECODETRANSLATEDTEXT	LANG	if _n_ = 1 then do; retain pattern1ID pattern2ID; pattern1 = "m...
4	CONDITIONDEFTRANSLATEDTEXT	LANG	if _n_ = 1 then do; retain pattern1ID pattern2ID; pattern1 = "m...
5	FORMDEFTRANSLATEDTEXT	LANG	if _n_ = 1 then do; retain pattern1ID pattern2ID; pattern1 = "m...
6	ITEMDEFTRANSLATEDTEXT	LANG	if _n_ = 1 then do; retain pattern1ID pattern2ID; pattern1 = "m...

SAS Clinical Standards Toolkit Metadata

Reference_Tables & Source_Tables

Reference_tables contains ALL standard specific table information. **Source_tables** contains study specific table/domain information and is created from reference_tables. Determines tables to be validated. For ODM, information comes from the ODM SAS Data Model.

	 table	 label	 standard	 standard version	 xmlelementname	 keys
1	ADMINDATA	Administrative Information	CDISC-ODM	1.3.0	AdminData	FK_ODM STUDYOID
2	ANNOTATION	Annotations associated with...	CDISC-ODM	1.3.0	Annotation	PARENTTYPE PARENTKEY ID
3	ANNOTATIONFLAG	Machine-processable annota...	CDISC-ODM	1.3.0	AnnotationFlag	FK_ANNOTATION FLAGVALU
4	ASSOCIATION	Documents links between re...	CDISC-ODM	1.3.0	Association	FK_ODM STUDYOID METAD
5	AUDITRECORD	Audit information for data ch...	CDISC-ODM	1.3.0	AuditRecord	PARENTTYPE PARENTKEY
6	CLINICALDATA	Clinical data information	CDISC-ODM	1.3.0	ClinicalData	FK_ODM STUDYOID METAD
7	CLITEMDECODETRA...	Codelist value language-spe...	CDISC-ODM	1.3.0	CLItemDecodeTrans...	FK_CODELISTITEMS LANG T
8	CODELISTITEMS	Coded codelist values	CDISC-ODM	1.3.0	CodeListItems	FK_CODELISTS CODEDVALU
9	CODELISTS	Codelist metadata	CDISC-ODM	1.3.0	CodeLists	FK_METADATAVERSION OID
10	CONDITIONEFFOR...	Condition expression	CDISC-ODM	1.3.0	ConditionDefFormal...	FK_CONDITIONDEFS CONTI
11	CONDITIONDEFS	Conditions when data notcol...	CDISC-ODM	1.3.0	ConditionDefs	FK_METADATAVERSION OID
12	CONDITIONDEFTRAN...	Condition language-specific t...	CDISC-ODM	1.3.0	ConditionDefTransla...	FK_CONDITIONDEFS LANG

SAS Clinical Standards Toolkit Metadata

Reference_Columns & Source_Columns

Reference columns contains all **standard specific** table/domain column information. **Source_columns** contains **study specific** table/domain column information and is created from reference_columns. Determines columns to be validated. For ODM, information comes from the ODM SAS Data Model.

	⚠️ sasref	⚠️ table	⚠️ column	⚠️ label	123 order	⚠️ type	123 length
104	REFDATA	ITEMDEFS	OID	Unique identifier for this i...	1	C	64
105	REFDATA	ITEMDEFS	NAME	Item (variable) name	2	C	128
106	REFDATA	ITEMDEFS	DATATYPE	Item (variable) data type...	3	C	18
107	REFDATA	ITEMDEFS	LENGTH	Item (variable) length	4	N	8
108	REFDATA	ITEMDEFS	SIGNIFICANTDI...	Number of decimal digits...	5	N	8
109	REFDATA	ITEMDEFS	SASFIELDNAME	SAS column name	6	C	8
110	REFDATA	ITEMDEFS	SDSVARNAME	Item (variable) name with...	7	C	8

	⚠️ standard	⚠️ standardversion	⚠️ core	⚠️ xmlcodelist	⚠️ xmlattributename
104	CDISC-ODM	1.3.0	Req		OID
105	CDISC-ODM	1.3.0	Req		Name
106	CDISC-ODM	1.3.0	Req	IDTYPE	DataType
107	CDISC-ODM	1.3.0	Opt		Length
108	CDISC-ODM	1.3.0	Opt		SignificantDigits
109	CDISC-ODM	1.3.0	Opt		SASFieldName
110	CDISC-ODM	1.3.0	Opt		SDSVarName



Toolkit Processes

CST typical program

- Define global macro variables ("properties")
 - %LET statements
 - %*cst_setStandardProperties*(_cstStandard=CST-FRAMEWORK,_cstSubType=initialize);
- Define inputs / outputs
(libnames, filenames, SAS autocall macros, ...)
 - 1. Create SASReferences dataset
 - 2. %*cstutil_processsetup*();
(default: use WORK.SASReferences)
- Run process specific macro:
%*odm_read*
%*odm_write*
%*odm_validate*
%*odm_xmlvalidate*

Reading and writing ODM XML files

- Reading and writing ODM XML uses an intermediate 'flat' XML Cube
- This 'flat' XML Cube can be easily transformed to the 2-dimensional SAS data sets

Reading and writing ODM XML files

```
<CodeList OID="CL.$AESEV" SASFormatName="$AESEV" Name="$AESEV" DataType="text">
  <CodeListItem CodedValue='1'>
    <Decode>
      <TranslatedText xml:lang="en">Mild</TranslatedText>
    </Decode>
  </CodeListItem>
  <CodeListItem CodedValue='2'>
    <Decode>
      <TranslatedText xml:lang="en">Moderate</TranslatedText>
    </Decode>
  </CodeListItem>
  <CodeListItem CodedValue='3'>
    <Decode>
      <TranslatedText xml:lang="en">Severe</TranslatedText>
    </Decode>
  </CodeListItem>
  <CodeListItem CodedValue='4'>
    <Decode>
      <TranslatedText xml:lang="en">Life Threatening</TranslatedText>
    </Decode>
  </CodeListItem>
</CodeList>
```

Reading and writing ODM XML files

```
<CodeLists>
  <OID>CL.$AESEV</OID>
  <Name>$AESEV</Name>
  <DataType>text</DataType>
  <SASFormatName>$AESEV</SASFormatName>
  <FK_MetaDataVersion>MetaDataVersion.OID.1</FK_MetaDataVersion>
</CodeLists>
```

```
<CodeListItems>
  <OID>N68519</OID>
  <CodedValue>1</CodedValue>
  <FK_CodeLists>CL.$AESEV</FK_CodeLists>
  <Rank/>
</CodeListItems>
<CodeListItems>
  <OID>N68530</OID>
  <CodedValue>2</CodedValue>
  <FK_CodeLists>CL.$AESEV</FK_CodeLists>
  <Rank/>
</CodeListItems>
```

Reading and writing ODM XML files

```
<CLItemDecodeTranslatedText>
  <TranslatedText>Mild</TranslatedText>
  <lang>en</lang>
  <FK_CodeListItems>N68519</FK_CodeListItems>
</CLItemDecodeTranslatedText>
<CLItemDecodeTranslatedText>
  <TranslatedText>Moderate</TranslatedText>
  <lang>en</lang>
  <FK_CodeListItems>N68530</FK_CodeListItems>
</CLItemDecodeTranslatedText>
<CLItemDecodeTranslatedText>
  <TranslatedText>Severe</TranslatedText>
  <lang>en</lang>
  <FK_CodeListItems>N68541</FK_CodeListItems>
</CLItemDecodeTranslatedText>
<CLItemDecodeTranslatedText>
  <TranslatedText>Life Threatening</TranslatedText>
  <lang>en</lang>
  <FK_CodeListItems>N68552</FK_CodeListItems>
</CLItemDecodeTranslatedText>
```



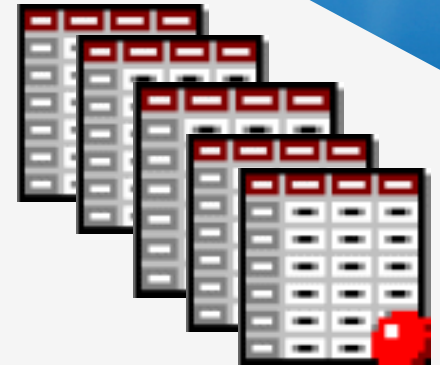
Java



Java



**SAS XML
Mapper**



```
%cstutl_writeodmcubexml();  
(DATA_NULL_)
```

**ODM
SAS data**



Reading clinical data from ODM

```
<ItemDataFloat ItemOID="ID.VS.VSSTRESN">76</ItemDataFloat>  
<ItemData ItemOID="ID.AE.AETERM" Value="HEADACHE" />
```

OID	ItemOID	Value	IsNull	ItemDataType
N80804	ID.VS.VSSTRESN	76		Float

OID	ItemOID	Value ▲	IsNull	ItemDataType
N80940	ID.AETERM	HEADACHE		

Validating ODM XML files

- Schema Validation: against ODM XML file
 - %odm_xmlvalidate();
- Validating the SAS data set representation
 - %odm_validate();

Validating ODM XML files

- Schema Validation: against ODM XML file

```
<ItemDef OID="ItemDef.OID.DM.RFSTDTC" Name="RFST  
    SASFieldName="RFSTDTC"  
    Comment="Reference Start Date/time for  
Usually equivalent to date/time when subject was  
for all randomized subjects; will be null for al  
date requires, such as screen failures or unassi  
<Itemdef OID="ItemDef.OID.DM.SEX" Name="SEX" Dat  
    SASFieldName="SEX"  
    Comment="Sex of the subject.">  
    <CodeListRef CodeListOID="CodeLists.OID.SEX"/>  
</Itemdef>  
<ItemDef OID="ItemDef.OID.DM.SITEID" Name="SITEI  
    SASFieldName="SITEID"  
    Comment="Unique identifier for a site w
```

Validating ODM XML files

- Schema Validation: against ODM XML file

VIEWTABLE: Results.Read_results

	resultid	srcdata	message	resultseverity
32	ODM0003	XML VALIDATION	(Line 441/Column 136) cvc-complex-type.2.4.a: Invalid content was found starting with element 'Itemdef'. One of '{'http://www.cdisc.org/ns/odm/v1.3':ItemDef, 'http://www.cdisc.org/ns/odm/v1.3':CodeList, 'http://www.cdisc.org/ns/odm/v1.3':ImputationMethod, 'http://www.cdisc.org/ns/odm/v1.3':Presentation, 'http://www.cdisc.org/ns/odm/v1.3':ConditionDef, 'http://www.cdisc.org/ns/odm/v1.3':MethodDef}' is expected.	Error
33	ODM0002	XML TRANSFORMER	Document validation failed	Warning

- This file can still be READ, but the 'invalid' Itemdef will be **ignored**.

Validating the SAS data set representation

- Validating the SAS representation: %odm_validate();

```
<ItemGroupDef OID="ItemGroupDefs.OID.DM" Name="DM" Repeating="No"
  IsReferenceData="N" SASDatasetName="DM" Domain="DM"
  Purpose="Tabulation">
  <ItemRef ItemOID="ItemDef.DM.AGEU" Mandatory="No" OrderNumber="11" />
  <ItemRef ItemOID="ItemDef.DM.AGEU" Mandatory="No" OrderNumber="12" />
...
</ItemGroupDef>
...
<ItemDef OID="ItemDef.DM.AGEU" Name="AGEU" DataType="string" Length="10"
  SASFieldName="AGEU" Comment="Units associated with AGE. ">
  <CodeListRef CodeListOID="CodeLists.OID.AGEU"/>
</ItemDef>

<CodeList OID="CodeLists.OID.AGEUNIT" Name="AGEU" DataType="string"
  SASFormatName="AGEU">
  <EnumeratedItem CodedValue="YEARS" />
</CodeList>
```

Validating the SAS data set representation

- Validating the SAS representation: %odm_validate();

VIEWTABLE: Results.Validation_results

	resultid	checkid	srcdata	message	resultseverity	actual
41	ODM0100	ODM0100	SRCDATA.ITEMGROUPDEFITEMREFS	No two values for the source column can be equivalent within the same source data set	Error	keys=FK_ITEMGROUPDEFS ITEMROID
201	ODM0110	ODM0110	SRCDATA.ITEMDEFS (SRCDATA.CODELISTS)	The foreign key OID does not have a corresponding value in the target data set SRCDATA.ITEMDEFS	Error	CODELISTREF=CodeLists.OID.AGEU
323	ODM0217	ODM0217	SRCDATA.CODELISTS	A CodeList contains a SASFormatName value that does not have the correct format: CodeList datatype is text or string and the FormatName does not start with \$.	Error	DATATYPE=string,SASFORMATNAME=AGEU



Questions ?

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