

SAS® Clinical Standards Toolkit: define.xml and Value Level Metadata

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Agenda

- What is **define.xml** (**CRT-DDS**)?
- The **CRT-DDS** SAS Data Model
- What is SAS Clinical Standards Toolkit (**CST**)?
- Create **define.xml** from **SDTM 3.1.2** metadata
- Implementing **Value Level Metadata**

What is the define.xml (CRT-DDS)?

- Case Report Tabulation Data Specification (**CRT-DDS**, or **define.xml**): Production version: **1.0.0**
CRT-DDS **1.0.0** is the only production version right now
- Extension of the CDISC Operational Data Model (**ODM**), an **XML** specification to facilitate the archival and interchange of the metadata and data for clinical research
- Maintained by CDISC's **XML Technologies Team** (formerly known as the ODM team)
- New **Define-XML v2.0** released soon with additional metadata support (based on ODM 1.3.1)

What is the define.xml (CRT-DDS)?



<http://www.cdisc.org/define-xml>



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Model

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Define.XML

FDA Adds CDISC ODM Define.xml to Study Data Specifications

The FDA has now included the CDISC Case Report Tabulation Data Definition Specification (define.xml), which is based on the CDISC ODM, as part of the eCTD Study Data Specifications for the eCTD for submissions using the SDTM. The revised specifications are [available here](#).

Case Report Tabulation Data Definition Specification (CRT-DDS, also called define.xml) Final Version 1.0

CRT-DDS Released for Implementation February 10, 2005.

The CDISC define.xml Team has published the Case Report Tabulation Data Definition Specification (define.xml) Version 1.0 for

What is the define.xml (CRT-DDS)?

The specifications

 <http://www.cdisc.org/define-xml>

Case Report Tabulation Data Definition Specification (define.xml)

Prepared by the
CDISC define.xml Team

Principal Editor: William Qubeck
Principal Contributors: Sally Cassells, Anthony Friebel, and the define.xml team

Notes to Readers

This version of the Case Report Tabulation Data Definition Specification supersedes all prior versions. Version 1.0.0 reflects changes from a comment period through the Health Level 7 (HL7) Regulated Clinical Research Information Management Technical Committee (RCRIM) in December 2003 (www.hl7.org) and CDISC's website in September 2004 as well as the work done by the define.xml team to add functionality, features, and additional documentation.

Version 1.0.0 incorporated the applicable comments, suggestions, and corrections received from the two comment periods specified above and is the official implementation version.

Revision History

Date	Version	Summary of Changes	Primary Authors
2005-02-05	1.0.0	This is the official implementation version of the Case Report Tabulation Data Definition specification.	The define.xml team
2005-02-09	1.0.0	Administrative update.	Anthony Friebel, William Qubeck, Sally Cassells

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



Clinical Data Interchange Standards Consortium

Specification for the Operational Data Model (ODM)

Version 1.2
Source File: ODM-1.2.5.adtd
Last Update: 19 Dec 2003 10:10 AM

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An official copy of this document is available at <http://www.cdisc.org/models/odm/v1.2/ODM1-2-0.html>

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What is the define.xml (CRT-DDS)?

Metadata Submission Guidelines



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

Study Data Tabulation Model Metadata Submission Guidelines (SDTM-MSG)

Prepared by the CDISC SDS Metadata Team

Notes to Readers

This is Version 1.0 of the Metadata Submissions Guidelines created by the CDISC Submission Data Standards Metadata subteam.

Revision History

Date	Version	Summary of Changes
2010-05-14	1.0 Draft	• Original draft for comment
2011-12-31	1.0 Final	• Final version 1.0 released

What is the define.xml (CRT-DDS)?

XML Schemas in Simple Terms

- Defines elements, attributes, data types etc. and their relationships
- Provides the specification for an XML document
- Enables validation of XML documents
- Important: an XML schema is not able to verify all business rules in the specification!!



What is the define.xml (CRT-DDS)?

<http://www.cdisc.org/define-xml>



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Define.XML

XML Schema Validation for Define.xml White Paper

The XML Schema Validation for Define.xml white paper provides guidance on validating define.xml version 1.0 documents against the define.xml XML schemas. It proposes practices and tools to improve define.xml schema validation. The goal is to foster more consistent validation results in order to facilitate regulatory submissions and interchange of define.xml documents. The document does not include any define.xml specifications or recommendations for creating define.xml content.

[XML Schema Validation for Define.xml \(pdf\)](#)

This zip file packages 3 define.xml version 1.0 examples with copies of the schemas for testing define.xml validation.

[Define.xml Validation \(zip\)](#)

STANDARDS

Study Data Tabulation Model

Operational Data Model

Define.XML

Study/Trial Design Model

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ADaM

Protocol

Terminology

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Therapeutic Area Standards

define.xml – content - metadata

- **Domain Level metadata**
- **Variable Level metadata**
- **Value Level metadata**
- **Code List metadata**
- **Computational Methods metadata**
- **Documents metadata (aCRF)**

define.xml – Domain level metadata

```
<ItemGroupDef
  OID="IG.MH" Name="MH" Repeating="Yes"
  IsReferenceData="No"
  SASDatasetName="MH"
  Purpose="Tabulation"
  def:Label="Medical History"
  def:Structure="One record per medical history event per subject"
  def:DomainKeys="STUDYID, USUBJID, MHCAT, MHTERM, MHSTDTC"
  def:Class="EVENTS"
  def:ArchiveLocationID="Location.MH">

  <ItemRef ItemOID="I.STUDYID"
    OrderNumber="1" Mandatory="Yes" Role="IDENTIFIER" />
  <ItemRef ItemOID="I.DOMAIN"
    OrderNumber="2" Mandatory="Yes" Role="IDENTIFIER" />
  <ItemRef ItemOID="I.USUBJID"
    OrderNumber="3" Mandatory="Yes" Role="IDENTIFIER" />
  ...
  <ItemRef ItemOID="I.MHTERM"
    OrderNumber="8" Mandatory="Yes" Role="TOPIC" />
  ...

  <def:leaf ID="Location.MH" xlink:href="mh.xpt">
    <def:title>mh.xpt</def:title>
  </def:leaf>
</ItemGroupDef>
```

define.xml – Variable level metadata

```
<ItemRef ItemOID="I.VSTESTCD" OrderNumber="6" Mandatory="Yes"  
  Role="TOPIC" RoleCodeListOID="RoleCodeList" />
```

```
<ItemRef ItemOID="I.VSBLFL" OrderNumber="14" Mandatory="No"  
  Role="RECORD QUALIFIER" RoleCodeListOID="RoleCodeList" />
```

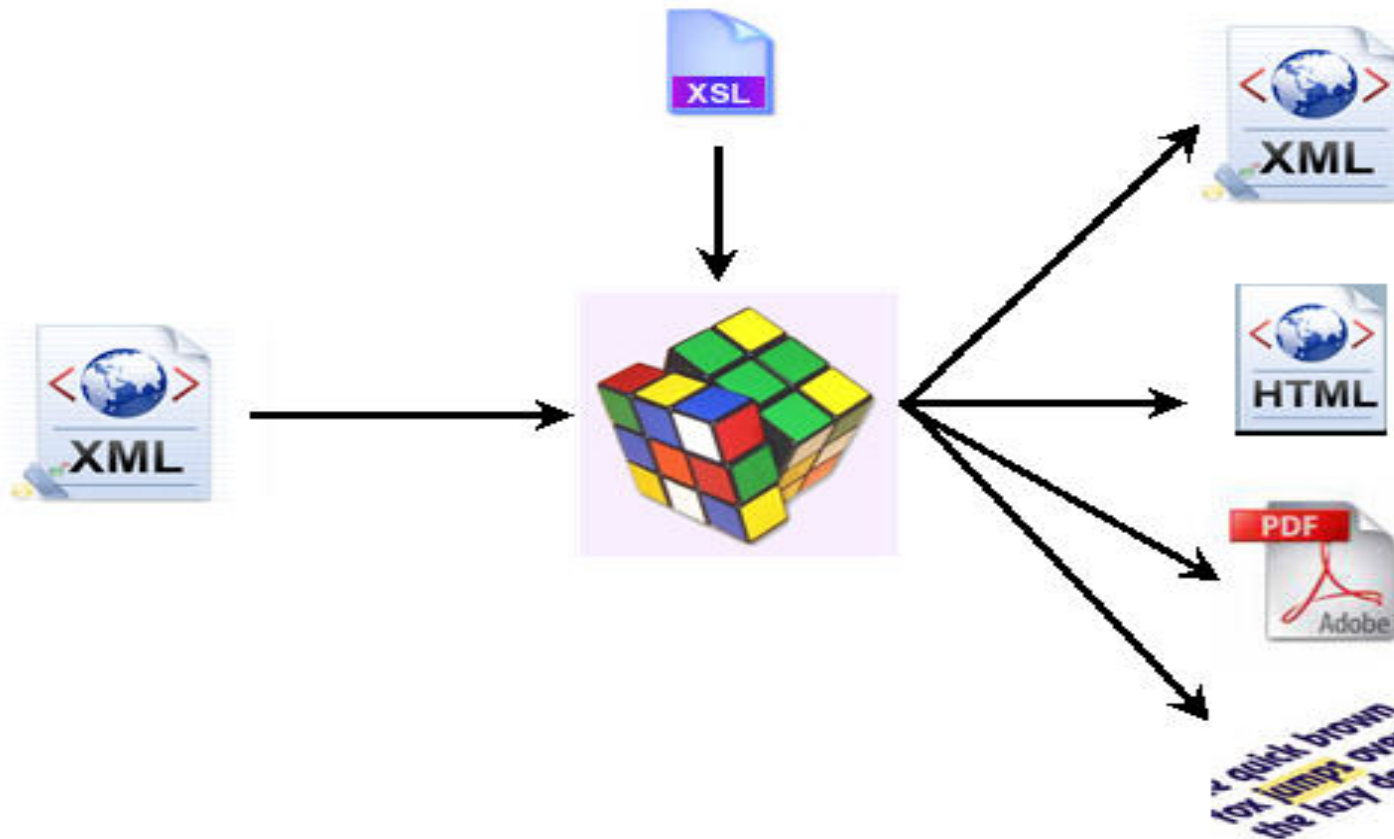
```
<ItemDef OID="I.VSTESTCD"  
  Name="VSTESTCD" DataType="text"  
  Length="8" Origin="CRF Page 9"  
  def:Label="Vital Signs Test Short Name">  
    <def:ValueListRef ValueListOID="VL.VSTESTCD" />  
</ItemDef>
```

...

```
<ItemDef OID="I.VSBLFL" Name="VSBLFL" DataType="text" Length="1"  
  Origin="DERIVED" Comment="Derivation of baseline: Safety patients only: VSBLFL=Y  
  for last non missing record on or before the first dose date (RFSTDTC)."  
  def:Label="Baseline Flag"  
  def:ComputationMethodOID="CM.VSBLFL">  
    <CodeListRef CodeListOID="CL.NY" />  
</ItemDef>
```

What is the define.xml (CRT-DDS)?

- define.xml contains **metadata** and is **machine** readable
- define.xml becomes **human** readable with a **stylesheet**
- The stylesheet is for display, but is **not** the standard.



What is the define.xml (CRT-DDS)?

define.xml becomes **human** readable with an **XSL** stylesheet

Datasets for Study 1234					
Dataset	Description	Structure	Purpose	Keys	Location
DM	Demographics	Special Purpose - One record per event per subject	Tabulation	STUDYID, USUBJID	crt/datasets/1234/dm.xpt
TE	Trial Elements	Trial Design - One Record Per Element	Tabulation	STUDYID, ELEMENT	crt/datasets/1234/te.xpt
TA	Trial Arms	Trial Design - One Record per Element for each Arm	Tabulation	STUDYID, ARM	crt/datasets/1234/ta.xpt
TV	Trial Visits	Trial Design - One Record per Visit per Arm	Tabulation	STUDYID, VISIT	crt/datasets/1234/tv.xpt
SE	Subject Elements	Study Design - One Record Per Subject Element	Tabulation	STUDYID, ELEMENT	crt/datasets/1234/se.xpt
SV	Subject Visits	Study Design - One Record Per Subject Visit	Tabulation	STUDYID, VISIT	crt/datasets/1234/sv.xpt
EX	Exposure	Interventions - One record per constant dosing interval per subject	Tabulation	USUBJID, EXTRT, EXSEQ	crt/datasets/1234/ex.xpt
CM	Concomitant Medications	Interventions - One record per event per subject	Tabulation	USUBJID, CMTRT, CMSEQ	crt/datasets/1234/cm.xpt
SU	Substance Use	Interventions - One record per substance use type per subject	Tabulation	USUBJID, SUTRT, SUSEQ	crt/datasets/1234/su.xpt
AE	Adverse Events	Events - One record per event per subject	Tabulation	USUBJID, AETERM, AESEQ	crt/datasets/1234/ae.xpt
DS	Disposition	Events - One record per disposition status or protocol milestone per subject	Tabulation	USUBJID, DSTERM, DSSEQ	crt/datasets/1234/ds.xpt
MH	Medical History	Events - One record per event per subject	Tabulation	USUBJID, MHTERM, MHSEQ	crt/datasets/1234/mh.xpt
EG	ECG Test Results	Findings - One record per event per subject	Tabulation	USUBJID, EGTESTCD, EGSEQ	crt/datasets/1234/eg.xpt
IE	Inclusion/Exclusion Exceptions	Findings - One record per event per subject	Tabulation	USUBJID, IETEST, IESEQ	crt/datasets/1234/ie.xpt
LB	Laboratory Tests	Findings - One record per lab test per subject	Tabulation	USUBJID, LBTESTCD, VISITNUM, TPTNUM, LBSEQ	crt/datasets/1234/lb.xpt

What is the define.xml (CRT-DDS)?

... and looks even fancier with a different **stylesheet**

Study 1234, Data Definitions						
Annotated Case Report Form Supplemental Data Definitions Document						
Datasets						
Demographics (DM)						
Trial Elements (TE)						
Trial Arms (TA)						
Trial Visits (TV)						
Subject Elements (SE)						
Subject Visits (SV)						
Exposure (EX)						
Concomitant Medications (CM)						
Substance Use (SU)						
Adverse Events (AE)						
Disposition (DS)						
Medical History (MH)						
ECG Test Results (EG)						
Inclusion/Exclusion Exceptions (IE)						
Laboratory Tests (LB)						
Physical Examination (PE)						
Subject Characteristics (SC)						
Vital Signs (VS)						
Comments (CO)						
Value Level Metadata						
Computational Algorithms						
Controlled Terminology						
Datasets for Study 1234						
Dataset	Description	Class	Structure	Purpose	Keys	Location
DM	Demographics	Special Purpose	One record per event per subject	Tabulation	STUDYID, USUBJID	crt/datasets/1234/dm.xpt
TE	Trial Elements	Trial Design	One Record Per Element	Tabulation	STUDYID, ELEMENT	crt/datasets/1234/te.xpt
TA	Trial Arms	Trial Design	One Record per Element for each Arm	Tabulation	STUDYID, ARM	crt/datasets/1234/ta.xpt
TV	Trial Visits	Trial Design	One Record per Visit per Arm	Tabulation	STUDYID, VISIT	crt/datasets/1234/tv.xpt
SE	Subject Elements	Study Design	One Record Per Subject Element	Tabulation	STUDYID, ELEMENT	crt/datasets/1234/se.xpt
SV	Subject Visits	Study Design	One Record Per Subject Visit	Tabulation	STUDYID, VISIT	crt/datasets/1234/sv.xpt
EX	Exposure	Interventions	One record per constant dosing interval per subject	Tabulation	USUBJID, EXTRT, EXSEQ	crt/datasets/1234/ex.xpt
CM	Concomitant Medications	Interventions	One record per event per subject	Tabulation	USUBJID, CMTRT, CMSEQ	crt/datasets/1234/cm.xpt
SU	Substance Use	Interventions	One record per substance use type per subject	Tabulation	USUBJID, SUTRT, SUSEQ	crt/datasets/1234/su.xpt
AE	Adverse Events	Events	One record per event per subject	Tabulation	USUBJID, AETERM, AESEQ	crt/datasets/1234/ae.xpt
DS	Disposition	Events	One record per disposition	Tabulation	USUBJID, DSTERM, DSSEQ	crt/datasets/1234/ds.xpt



The CRT-DDS SAS Data Model

The CRT-DDS SAS Data Model

- define.xml has a deep hierarchy
- define.xml contains many relations

```
<ItemGroupDef OID="MH"  
  Name="MH" Repeating="Yes" IsReferenceData="No"  
  Purpose="Tabulation" def:Label="Medical History"  
  def:Structure="One record per medical history event per subject"  
  def:DomainKeys="STUDYID, USUBJID, MHCAT, MHTERM, MHSTDTC"  
  def:Class="EVENTS" def:ArchiveLocationID="Location.AE">  
  <ItemRef ItemOID="STUDYID" OrderNumber="1" Mandatory="Yes"  
    Role="IDENTIFIER" RoleCodeListOID="RoleCodeList" />  
  ...
```

```
    <def:leaf ID="Location.MH" xlink:href="mh.xpt">  
      <def:title>mh.xpt</def:title>  
    </def:leaf>  
  </ItemGroupDef>  
  ...
```

```
<ItemDef OID="STUDYID" Name="STUDYID" DataType="text" Length="7"  
  Origin="CRF Page 3" def:Label="Study Identifier" />
```

The CRT-DDS SAS Data Model

- SAS provides data model that represents CRT-DDS Version 1.0 format in 39 SAS data sets
20 of these are typically used for the define.xml (*)
- Patterned to match the XML element and attribute structure of the define.xml file
- XML element → SAS dataset
XML attribute → SAS variable

★  annotatedcrfs	★  clitemdecodetranslatedtext	★  codelistitems	★  codelists
★  computationmethods	★  definedocument	★  externalcodelists	 formdefarchlayouts
 formdefitemgrouprefs	 formdefs	 imputationmethods	 itemaliases
★  itemdefs	 itemgroupaliases	★  itemgroupdefitemrefs	★  itemgroupdefs
★  itemgroupleaf	★  itemgroupleaftitles	 itemmurefs	 itemquestionexternal
 itemquestiontranslatedtext	 itemrangechecks	 itemrangecheckvalues	 itemrole
★  itemvaluelistrefs	★  mdvleaf	★  mdvleaftitles	 measurementunits
★  metadataversion	 mutranslatedtext	 presentation	 protocoleventrefs
 rerrortranslatedtext	★  study	 studyeventdefs	 studyeventformrefs
★  supplementaldocs	★  valuelistitemrefs	★  valuelists	

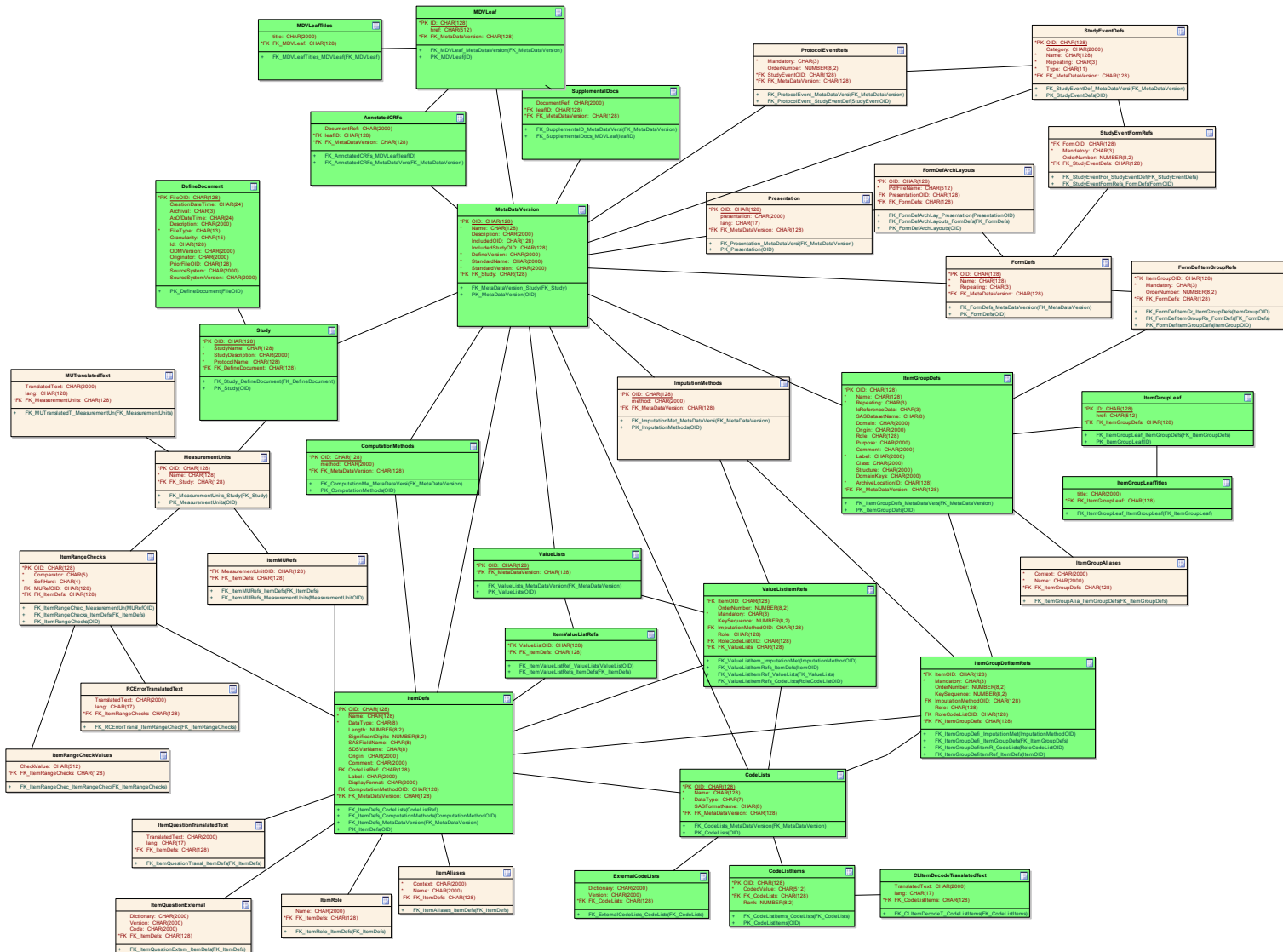
The CRT-DDS SAS Data Model

```
<ItemDef OID="COL10" Name="BRTHDTC" DataType="text" Length="64"  
SASFieldName="BRTHDTC" def:Label="Date/Time of Birth"/>  
<ItemDef OID="COL11" Name="AGE" DataType="float"  
Length="8" SASFieldName="AGE" def:Label="Age"/>  
<ItemDef OID="COL12" Name="AGEU" DataType="text"  
Length="10" SASFieldName="AGEU" def:Label="Age Units">  
<CodeListRef CodeListOID="AGEU"/>  
</ItemDef>
```

VIEWTABLE: sywork.Itemdefs

	OID	Name	DataType	Length	CodeListRef	label
10	COL10	BRTHDTC	text	64		Date/Time of Birth
11	COL11	AGE	float	8		Age
12	COL12	AGEU	text	10	AGEU	Age Units

The CRT-DDS SAS Data Model





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.
- A collection of “tools”, providing an initial set of standards and functionality that is evolving and growing with updates and releases.
- Designed as an integral part of Clinical Data Integration (CDI), but is available to all SAS users as open source SAS Macros.

What is the SAS Clinical Standards Toolkit?

- CDISC SDTM models available 3.1.1 and 3.1.2
- ADaM support
- Controlled Terminology (NCI)
- CRT-DDS (define.xml) capability
- ODM 1.3 import/export
- Flexible: customizable to fit various standards (there is no 'magic bullet' !)
- Available at no additional charge for SAS/Base customers



SDTM metadata → define.xml

CST typical program

- Define global macro variables ("properties")
 - `%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:
 - `%crtds_sdtmtodefine`
 - `%crtds_validate`
 - `%crtds_write`
 - `%crtds_xmlvalidate`
 - `%crtds_read`

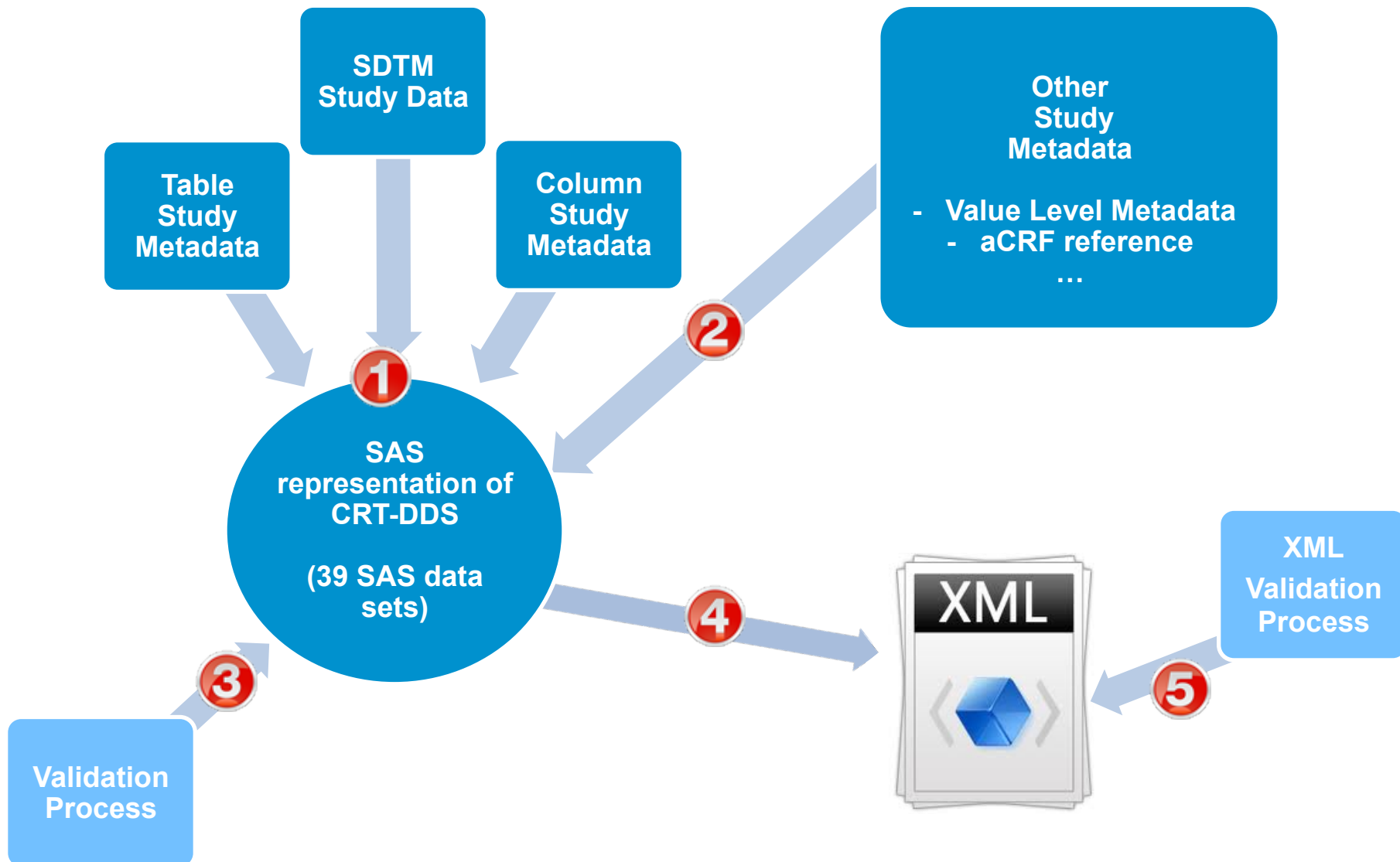
CRT-DDS macros for creating define.xml

- **%crtdds_sdtmtodefine** –
Create empty CRT-DDS SAS data sets and populates them based on SDTM sourcemetadata
- **%crtdds_validate** –
Validate CRT-DDS SAS data sets
- **%crtdds_write** –
Create define.xml from CRT-DDS SAS data sets
- **%crtdds_xmlvalidate** –
Validate define.xml against XML schema

CRT-DDS macros for creating define.xml

- **%crtdds_sdtmtodefine** –
Create 39 empty CRT-DDS SAS data sets and populates a selection of them based on SDTM sourcemetadata
- 20 of the 39 CRT-DDS datasets are needed for creating the define.xml for submission
- CST 1.4: **%crtdds_sdtmtodefine** will populate 12 of these data sets (no **Value Level Metadata**)
- CST 1.5: **%crtdds_sdtmtodefine** will populate all of the 20 data sets using more SDTM source metadata (including **Value Level Metadata**)

SDTM to define.xml



SDTM to define.xml – Source metadata

VIEWTABLE: Sdtmmeta.Source_study (Source Study Metadata)

	definedocumentname	sasref	studyname	protocolname	studydescription
1	define1	SRCDATA	study1	Protocol abc	first study

VIEWTABLE: Sdtmmeta.Source_tables (Source Table Metadata)

	SASref	Table	Label	Class	XmlPath	XmlTitle	Structure	Purpose	Keys
1	SRCDATA	AE	Adverse Events	Events	../transport/ae.xpt	Adverse Events SAS transport file	One record per adverse event per subject	Tabulation	STUDYID USUBJID AEDECOD AESTDTC
2	SRCDATA	CE	Clinical Events	Events	../transport/ce.xpt	Clinical Events SAS transport file	One record per event per subject	Tabulation	STUDYID USUBJID CETERM CESTDTC
3	SRCDATA	CM	Concomitant Medications	Interventions	../transport/cm.xpt	Concomitant Medications SAS transport file	One record per recorded medication occurrence or constant-dosing interval per subject	Tabulation	STUDYID USUBJID CMTRT CMSTDTC

VIEWTABLE: Sdtmmeta.Source_columns (Source Column Metadata)

	SASref	table	column	label	order	type	length	displayformat	xml datatype	xmlcodelist	core	origin	role
1	SRCDATA	AE	STUDYID	Study Identifier	1	C	40		text		Req		Identifier
2	SRCDATA	AE	DOMAIN	Domain Abbreviation	2	C	8		text		Req		Identifier
3	SRCDATA	AE	USUBJID	Unique Subject Identifier	3	C	40		text		Req		Identifier
4	SRCDATA	AE	AESEQ	Sequence Number	4	N	8		integer		Req		Identifier
5	SRCDATA	AE	AEGRPID	Group ID	5	C	40		text		Perm		Identifier
6	SRCDATA	AE	AEREFID	Reference ID	6	C	40		text		Perm		Identifier
7	SRCDATA	AE	AESPID	Sponsor-Defined Identifier	7	C	40		text		Perm		Identifier
8	SRCDATA	AE	AETERM	Reported Term for the Adverse Event	8	C	200		text		Req		Topic
9	SRCDATA	AE	AEMODIFY	Modified Reported Term	9	C	200		text		Perm		SynonymQualifier
10	SRCDATA	AE	AEDECOD	Dictionary-Derived Term	10	C	200		text		Req		SynonymQualifier
11	SRCDATA	AE	AECAT	Category for Adverse Event	11	C	40		text		Perm		GroupingQualifier
12	SRCDATA	AE	AESCAT	Subcategory for Adverse Event	12	C	40		text		Perm		GroupingQualifier
13	SRCDATA	AE	AEPRESP	Pre-Specified Adverse Event	13	C	2		text	NY	Perm		RecordQualifier
14	SRCDATA	AE	AEBODSYS	Body System or Organ Class	14	C	80		text		Exp		RecordQualifier
15	SRCDATA	AE	AELC	Location of Event	15	C	40		text	LOC	Perm		RecordQualifier
16	SRCDATA	AE	AESEV	Severity/Intensity	16	C	20		text	AESEV	Perm		RecordQualifier
17	SRCDATA	AE	AESER	Serious Event	17	C	2		text	NY	Exp		RecordQualifier
18	SRCDATA	AE	AEACN	Action Taken with Study Treatment	18	C	40		text	ACN	Exp		RecordQualifier

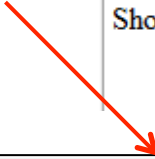


Value Level Metadata

Value Level Metadata

- Update the CRT-DDS SAS datasets to get Value level metadata

Vital Signs Dataset (VS)						
Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text			Identifier	Unique identifier for a study.
VSSPID	Sponsor-Defined Identifier	text			Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.
<u>VSTESTCD</u>	Vital Signs Test Short Name	text	<u>VSTESTCD</u>		Topic	Short name of the measurement, test, or examination described in VSTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in VSTESTCD cannot be longer than 8 characters, nor can it start with



VSTESTCD	DIABP	Diastolic Blood Pressure	integer		CRF Page 11
VSTESTCD	FRMSIZE	Frame Size	text		CRF Page 11
VSTESTCD	HRATE	Heart Rate	integer		CRF Page 11
VSTESTCD	PULBP	Pulse Pressure	integer		CRF Page 11
VSTESTCD	SYSBP	Systolic Blood Pressure	integer		CRF Page 11

Value Level Metadata

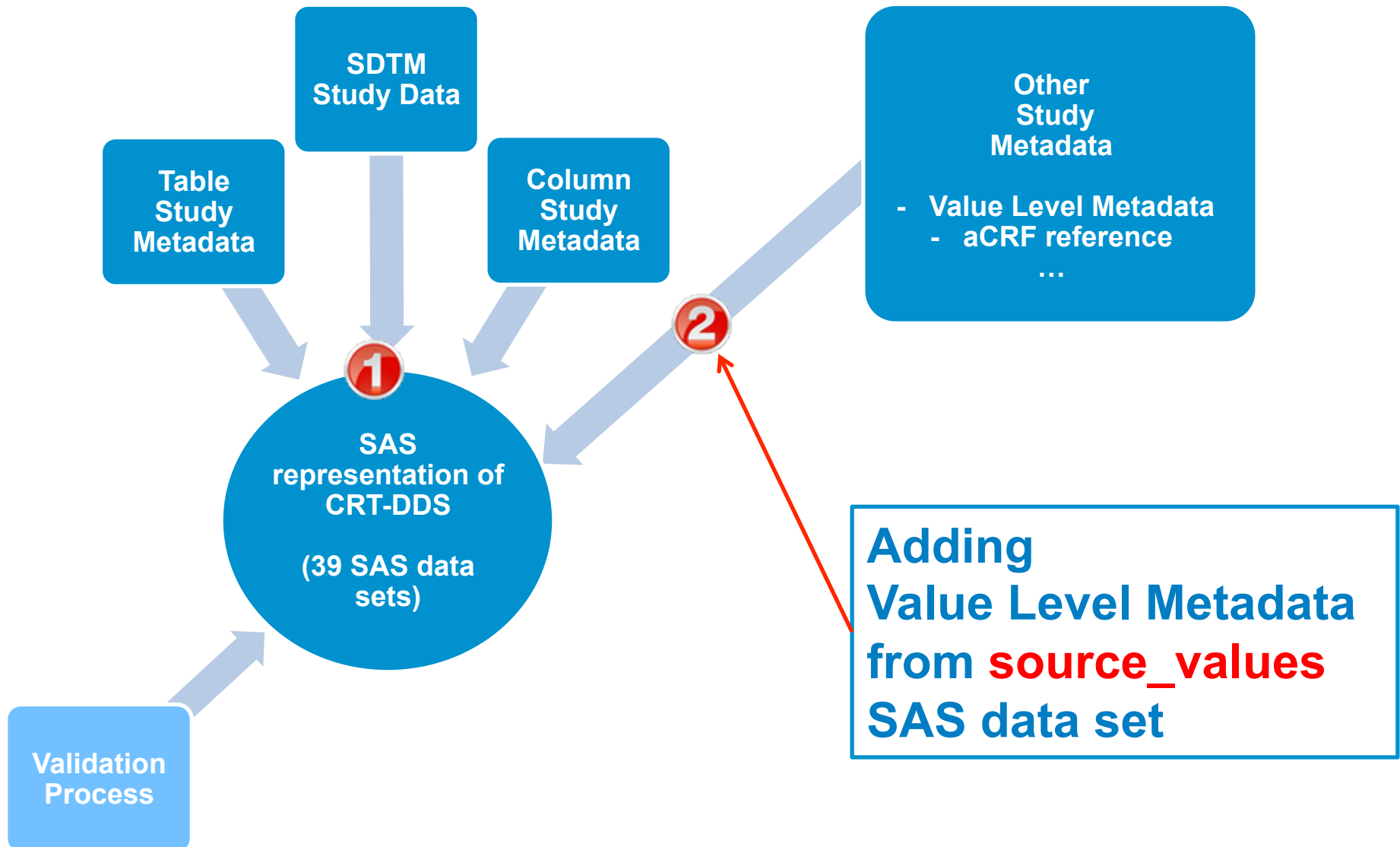
VIEWTABLE: Sdtmmeta.Source_columns (Source Column Metadata)

	SASref	table	column	label	order	type	length	displayfor	xmldatatype	xmlcodelist	core	origin
1	SRCDATA	AE	STUDYID	Study Identifier	1	C	40		text		Req	
2	SRCDATA	AE	DOMAIN	Domain Abbreviation	2	C	8		text		Req	
3	SRCDATA	AE	USUBJID	Unique Subject Identifier	3	C	40		text		Req	
4	SRCDATA	AE	AESQ	Sequence Number	4	N	8		integer		Req	
5	SRCDATA	AE	AEGRPID	Group ID	5	C	40		text		Perm	
6	SRCDATA	AE	AEREFID	Reference ID	6	C	40		text		Perm	
7	SRCDATA	AE	AESPID	Sponsor-Defined Identifier	7	C	40		text		Perm	
8	SRCDATA	AE	AETERM	Reported Term for the Adverse Event	8	C	200		text		Req	
9	SRCDATA	AE	AEMODIFY	Modified Reported Term	9	C	200		text		Perm	
10	SRCDATA	AE	AEDECOD	Dictionary-Derived Term	10	C	200		text		Req	
11	SRCDATA	AE	AECAT	Category for Adverse Event	11	C	40		text		Perm	
12	SRCDATA	AE	AESCAT	Subcategory for Adverse Event	12	C	40		text		Perm	

VIEWTABLE: Sdtmmeta.Source_values (Source Value Metadata)

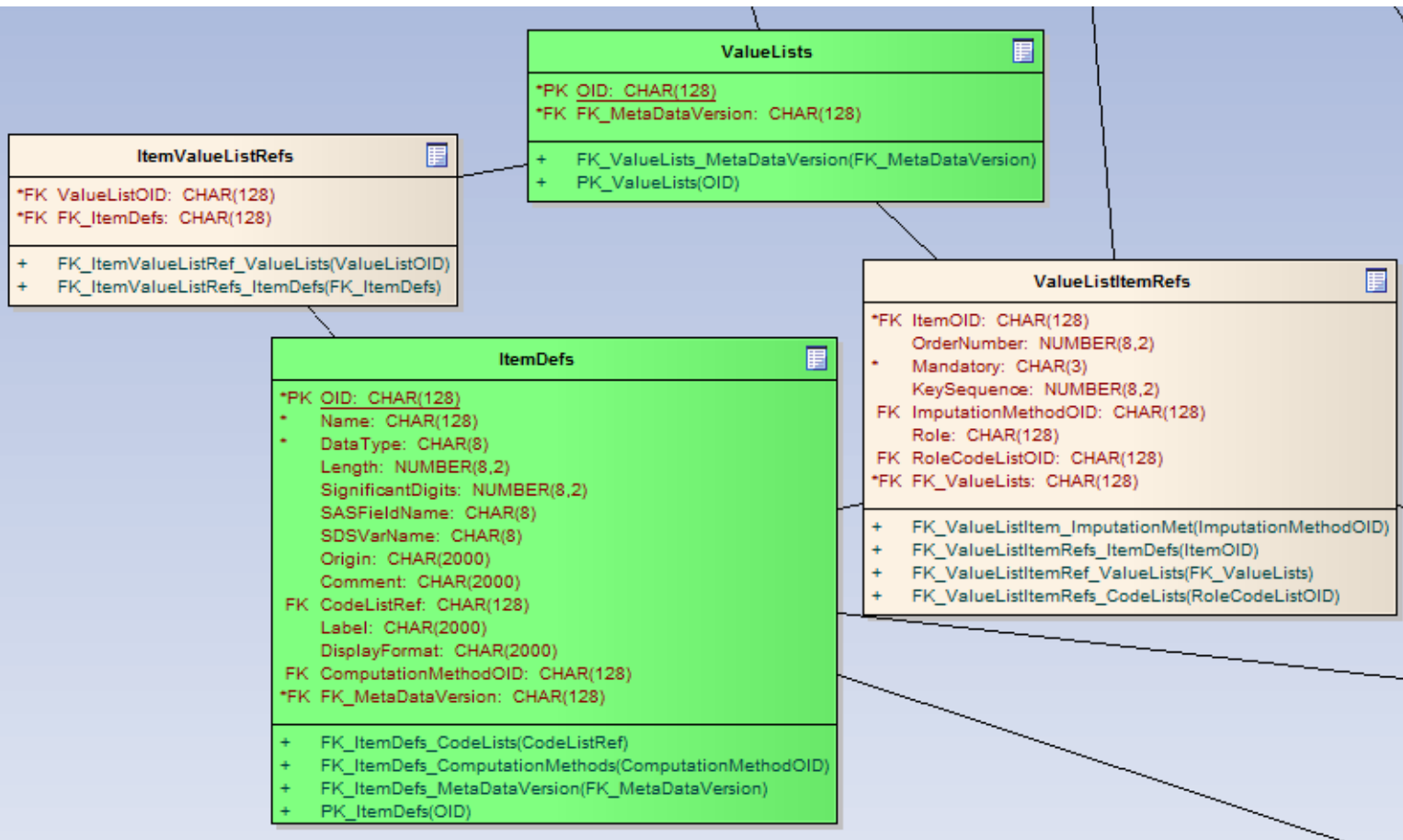
	SASref	table	column	value	label	order	type	length	displayfor	xmldatatype	xmlcodelist	core	origin
6	SRCDATA	IE	IETESTCD	INCL02	Acceptable chest X-Ray	1	C	2		text	NY	Perm	CRF Page 5
7	SRCDATA	IE	IETESTCD	INCL10	Systolic BP > 180	2	C	2		text	NY	Perm	CRF Page 5
8	SRCDATA	LB	LBTESTCD	CALCIUM	Calcium	1	N	8 8.2		float		Perm	eDT
9	SRCDATA	LB	LBTESTCD	CHLORIDE	Chloride	2	N	8		integer		Perm	eDT
10	SRCDATA	LB	LBTESTCD	POTASS	Potassium	3	N	8 8.2		float		Perm	eDT
11	SRCDATA	LB	LBTESTCD	SODIUM	Sodium	4	N	8		integer		Perm	eDT
12	SRCDATA	PE	PETESTCD	CARDIO	Cardiovascular	1	N	8		integer		Perm	CRF Page 10
13	SRCDATA	PE	PETESTCD	ENT	Ear/Nose/Throat	2	N	8		integer		Perm	CRF Page 10
14	SRCDATA	PE	PETESTCD	RESP	Respiratory	3	N	8		integer		Perm	CRF Page 10
15	SRCDATA	PE	PETESTCD	SKIN	Skin	4	N	8		integer		Perm	CRF Page 10
16	SRCDATA	SC	SCTESTCD	INITIALS	Initials	1	C	3		text		Perm	CRF Page 6
17	SRCDATA	SC	SCTESTCD	RACEOTH	Race, Other	2	C	10		text		Perm	CRF Page 6
18	SRCDATA	SUPPAE	QNAM	AECONIA	Interaction between addl and trial meds	1	C	2		text	NY	Perm	CRF Page 17
19	SRCDATA	SUPPAE	QNAM	AETRTEM	Treatment emergent	2	C	2		text	NY	Perm	CRF Page 17
20	SRCDATA	TI	IETESTCD	EXCL01	Systolic BP > 180	4	C	2		text	NY	Perm	CRF Page 14
21	SRCDATA	TI	IETESTCD	EXCL02	Diastolic BP > 120	3	C	2		text	NY	Perm	CRF Page 14
22	SRCDATA	TI	IETESTCD	INCL01	Age between 18 and 70	2	C	2		text	NY	Perm	CRF Page 14
23	SRCDATA	TI	IETESTCD	INCL02	Acceptable chest X-Ray	1	C	2		text	NY	Perm	CRF Page 14
24	SRCDATA	VS	VSTESTCD	DIABP	Diastolic Blood Pressure	1	N	8		integer		Perm	CRF Page 11
25	SRCDATA	VS	VSTESTCD	FRMSIZE	Frame Size	2	C	6		text		Perm	CRF Page 11
26	SRCDATA	VS	VSTESTCD	HRATE	Heart Rate	3	N	8		integer		Perm	CRF Page 11

SDTM to define.xml



Value Level Metadata

- Update the CRT-DDS SAS datasets:
 - » Value level metadata



Value Level Metadata

- Update the CRT-DDS SAS datasets to get Value level metadata
 - » Manual process in 1.4
 - » Automated in 1.5

ValueLists – contains id of value lists

ValueListItemRefs – contains id of each item in a value list

ItemValueListRefs – associates each value list item to a row in the ItemDefs dataset

ItemDefs – contains metadata for each id in ValueListItemRefs

SAS Clinical Standards Toolkit: resources

<http://support.sas.com/rnd/base/cdisc/cst/index.html>

Papers

These papers introduce you to SAS Clinical Standards Toolkit and can help you understand how it functions.

- [The Implementation of Nested Value Level Metadata in the SAS Representation of the CRT-DDS v1.0.0 Model in the SAS Clinical Standards Toolkit \(.pdf\)](#) by Lex Jansen, SAS Institute Inc., Cary, NC (SAS Institute white paper 2012)
- [Using the SAS Clinical Standards Toolkit 1.4 for define.xml creation \(.pdf\)](#) | and [workshop materials \(.zip\)](#) by Lex Jansen, SAS Institute Inc., Cary, NC (PharmaSUG 2012)

CST 1.4 Value Level Metadata example code

SAS Clinical Standards Toolkit: resources

<http://support.sas.com/rnd/base/cdisc/cst/index.html>



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CDISC Support

SAS® Clinical Standards Toolkit

The SAS® Clinical Standards Toolkit 1.4 provides support of multiple CDISC standards, including SDTM (3.1.1 and 3.1.2), CRTDDS (reading and creating define.xml files), ODM (reading and creating 1.3.0 xml files) and ADaM 2.1. This tool is the platform used by SAS to support Health and Life Sciences industry data model standards. SAS Clinical Standards Toolkit is under active development with multiple releases planned in its product roadmap.

The recent release of SAS Clinical Standards Toolkit 1.4 provides full support of the CDISC-ODM 1.3.0 standard (reading and creating ODM xml files), the CDISC ADaM 2.1 standard (ADSL, Basic Data Structure and Analysis Results Metadata templates, as well as version 1.1 of the ADaM validation checks), and a CDISC Controlled Terminology package that includes the cumulative set of terminology as posted to the [NCI FTP site](#) as of April 2011. This set of terminology is sufficient to support the CDISC-SDTM 3.1.2 and ADaM 2.1 standards.

SAS Clinical Standards Toolkit 1.4 is supported with SAS 9.3 on the following operating systems:

- Windows 32
- Windows x64
- Linux x64
- Solaris SPARC
- Solaris AMD
- HP-UX Itanium

The toolkit is a separately orderable component that is available at no additional charge to currently licensed SAS customers. Contact your SAS Account Representative concerning availability.

Ordering the Toolkit

SAS 9.3

SAS Clinical Standards Toolkit version 1.4 for SAS 9.3 must be ordered through normal channels. Contact your SAS representative to have SAS Clinical Standards Toolkit added to your existing SAS license(s) for no additional fee.

SAS Clinical Standards Toolkit: resources



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- SAS Clinical Standards Toolkit 1.4: Getting Started [\[PDF\]](#) (985KB)
- SAS Clinical Standards Toolkit 1.4: User's Guide [\[PDF\]](#) (14MB) | [\[HTML\]](#)

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- SAS Clinical Standards Toolkit 1.3: User's Guide [\[PDF\]](#) (5.26MB) | [\[HTML\]](#)

SAS Clinical Standards Toolkit 1.2

- SAS Clinical Standards Toolkit 1.2: User's Guide [\[PDF\]](#) (4.53MB)
- SAS Clinical Standards Toolkit 1.2: Quick Start for SDTM Validation for SAS 9.2 and SAS 9.1.3 [\[PDF\]](#) (323KB)
- SAS Clinical Standards Toolkit in SAS 9.1.3: Installation Instructions [\[PDF\]](#) (490KB)

SAS Clinical Standards Toolkit: resources

Papers

These papers introduce you to SAS Clinical Standards Toolkit and can help you understand how it functions.

- [The Implementation of Nested Value Level Metadata in the SAS Representation of the CRT-DDS v1.0.0 Model in the SAS Clinical Standards Toolkit \(.pdf\)](#) by Lex Jansen, SAS Institute Inc., Cary, NC (SAS Institute white paper 2012)
- [Using the SAS Clinical Standards Toolkit 1.4 for define.xml creation \(.pdf\)](#) | and [workshop materials \(.zip\)](#) by Lex Jansen, SAS Institute Inc., Cary, NC (PharmaSUG 2012)
- [How to Register a New Custom Standard within the Clinical Standards Toolkit \(.pdf\)](#) by Gene Lightfoot, SAS Institute Inc., Cary, NC (SAS Institute white paper 2011)
- [Using the SAS Clinical Standards Toolkit to Work with the CDISC ODM Model \(.pdf\)](#) by Lex Jansen, SAS Institute Inc., Cary, NC (PhUSE 2011)
- [Implementing ADaM Using SAS Clinical Standards Toolkit 1.4 \(.pdf\)](#) by Gene Lightfoot, SAS Institute Inc., Cary, NC (PhUSE 2011)
- [Implementing, Managing, and Validating a Clinical Standard Using SAS Clinical Standards Toolkit 1.3 \(.pdf\)](#) by Gene Lightfoot, SAS Institute Inc., Cary, NC (PhUSE 2010)
- [Define.xml - Tips and Techniques for Creating CRT-DDS \(.pdf\)](#) by Julie Maddox, SAS Institute Inc., Cary, NC, and Mark Lambrecht, SAS Institute Inc., Tervuren, Belgium (PhUSE 2010)
- [The SAS Clinical Standards Toolkit \(.pdf\)](#) by Dave Smith, SAS Institute Inc., Cary, NC (PhUSE 2009)
- [Introduction to SAS Clinical Standards Toolkit \(.pdf\)](#) by Andreas Mangold and Nicole Wachter, HMS Analytical Software GmbH, Heidelberg, Germany (PhUSE 2010)

Questions ?



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