Creating Define-XML v2 with the SAS Clinical Standards© Toolkit 1.6

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INTRODUCTION

- **Framework** to primarily support **Clinical Research** activities (CDISC).
- Designed as an integral part of **Clinical Data Integration** (CDI)
- Available to all licensed SAS customers as open source SAS Macros and metadata at no additional charge.
- Designed to supersede PROC CDISC
- Framework: designed to **customize** and **extend**

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INTRODUCTION

- 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, SEND
  - XML standards: Define-XML and ODM
  - Controlled Terminology (CDISC/NCI)

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INTRODUCTION

- Supported CDISC standards in Toolkit 1.6:
  - **SDTM** 3.1.1, 3.1.2, 3.1.3 and 3.2
  - **ADaM** 2.1 (ADSL, Basic Data Structure, ADAE and ADTTE) and Analysis Results Metadata templates; v1.1 of the ADaM validation checks)
  - **SEND** 3.0 (initial implementation)
  - **CRT-DDS** 1.0 (Define-XML - Create / Import / Validate)
  - **Define-XML** 2.0 (Create / Import / Validate)
  - **ODM** 1.3.0, 1.3.1 - Read / Write / Validate
  - **NCI CDISC Controlled Terminology** (December 2013) (import/export of ODM XML through CT 1.0 standard)

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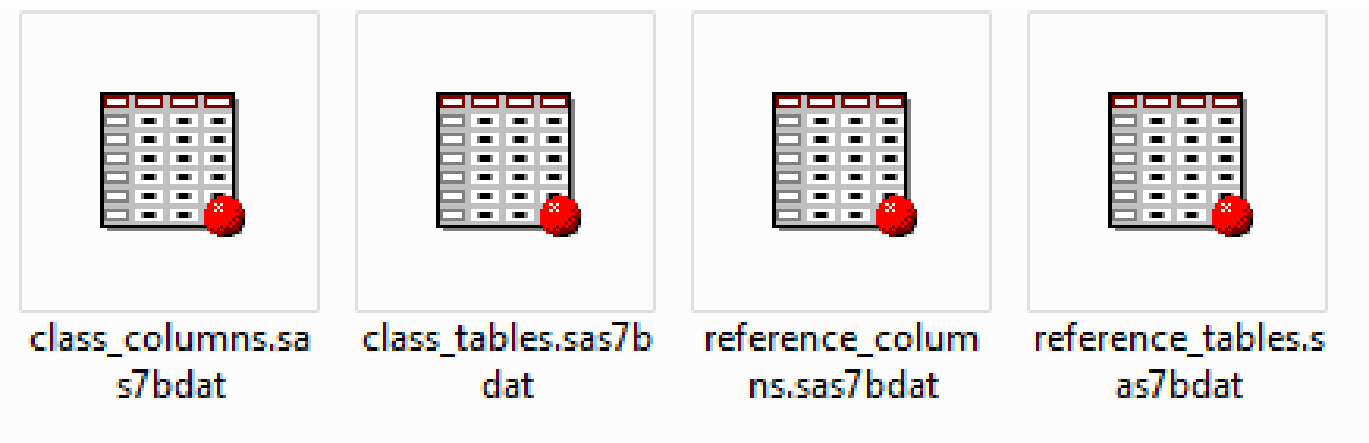
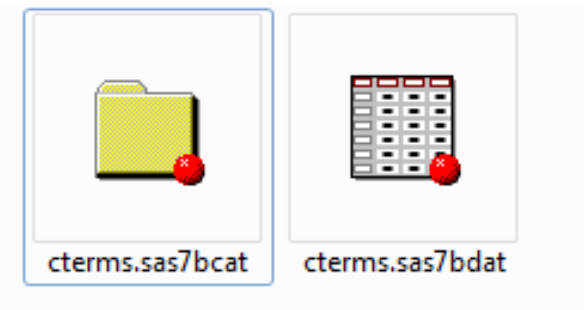
EXAMPLE: SDTM 3.1.2

- **SDTM** 3.1.2



- **CDISC NCI Controlled Terminology SDTM** 2013-12



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SDTM DATASET METADATA

	Table	Label	Class	XmlPath	XmlTitle	Structure	Purpose	Keys
1	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	CE	Clinical Events	Events	../transport/ce.xpt	Clinical Events SAS transport file	One record per event per subject	Tabulation	STUDYID USUBJID CETERM CESTDTC
3	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
4	CO	Comments	Special Purpose Domains	../transport/co.xpt	Comments SAS transport file	One record per comment per subject	Tabulation	STUDYID USUBJID COSEQ
5	DA	Drug Accountability	Findings	../transport/da.xpt	Drug Accountability SAS transport file	One record per drug accountability finding per subject	Tabulation	STUDYID USUBJID DATESTCD DADTC
6	DM	Demographics	Special Purpose Domains	../transport/dm.xpt	Demographics SAS transport file	One record per subject	Tabulation	STUDYID USUBJID
7	DS	Disposition	Events	../transport/ds.xpt	Disposition SAS transport file	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID USUBJID DSDECOD DSSTDTC
8	DV	Protocol Deviations	Events	../transport/dv.xpt	Protocol Deviations SAS transport file	One record per protocol deviation per subject	Tabulation	STUDYID USUBJID DVTERM DVSTDTC
9	EG	ECG Test Results	Findings	../transport/eg.xpt	ECG Test Results SAS transport file	One record per ECG observation per time point per visit per subject	Tabulation	STUDYID USUBJID EGTESTCD VISITNUM EGTPTREF EGTPTNUM
10	EX	Exposure	Interventions	../transport/ex.xpt	Exposure SAS transport file	One record per constant dosing interval per subject	Tabulation	STUDYID USUBJID EXTRT EXSTDTC
11	FA	Findings About	Findings About	../transport/fa.xpt	Findings About SAS transport file	One record per finding per object per time point per time point reference per visit per subject	Tabulation	STUDYID USUBJID FATESTCD FAOBJ VISITNUM FATPTREF FATPTNUM
12	IE	Inclusion/Exclusion Criterion Not Met	Findings	../transport/ie.xpt	Inclusion/Exclusion Criterion Not Met SAS transport file	One record per inclusion/exclusion criterion not met per subject	Tabulation	STUDYID USUBJID IETESTCD
					Laboratory Test	One record per analyte per		STUDYID USUBJID

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SDTM VARIABLE METADATA

	table	column	label	order	type	length	xmldatatype	xmlcodelist	core	origin	role	algorithm
1	AE	STUDYID	Study Identifier	1	C	40	text		Req		Identifier	
2	AE	DOMAIN	Domain Abbreviation	2	C	8	text		Req		Identifier	
3	AE	USUBJID	Unique Subject Identifier	3	C	40	text		Req		Identifier	
4	AE	AESEQ	Sequence Number	4	N	8	integer		Req		Identifier	
5	AE	AEGRPID	Group ID	5	C	40	text		Perm		Identifier	
6	AE	AEREFID	Reference ID	6	C	40	text		Perm		Identifier	
7	AE	AESPID	Sponsor-Defined Identifier	7	C	40	text		Perm		Identifier	
8	AE	AETERM	Reported Term for the Adverse Event	8	C	200	text		Req		Topic	
9	AE	AEMODIFY	Modified Reported Term	9	C	200	text		Perm		SynonymQualifier	
10	AE	AEDECOD	Dictionary-Derived Term	10	C	200	text		Req		SynonymQualifier	
11	AE	AECAT	Category for Adverse Event	11	C	40	text		Perm		GroupingQualifier	
12	AE	AESCAT	Subcategory for Adverse Event	12	C	40	text		Perm		GroupingQualifier	
13	AE	AEPRESP	Pre-Specified Adverse Event	13	C	2	text	NY	Perm		RecordQualifier	
14	AE	AEBODSYS	Body System or Organ Class	14	C	80	text		Exp		RecordQualifier	
15	AE	AELOC	Location of Event	15	C	100	text	LOC	Perm		RecordQualifier	
16	AE	AESEV	Severity/Intensity	16	C	20	text	AESEV	Perm		RecordQualifier	
17	AE	AESER	Serious Event	17	C	2	text	NY	Exp		RecordQualifier	
18	AE	AEACN	Action Taken with Study Treatment	18	C	40	text	ACN	Exp		RecordQualifier	
19	AE	AEACNOTH	Other Action Taken	19	C	200	text		Perm		RecordQualifier	
20	AE	AEREL	Causality	20	C	40	text		Exp		RecordQualifier	
21	AE	AERELNST	Relationship to Non-Study Treatment	21	C	40	text		Perm		RecordQualifier	
22	AE	AEPATT	Pattern of Adverse Event	22	C	20	text		Perm		RecordQualifier	
23	AE	AEOUT	Outcome of Adverse Event	23	C	40	text	OUT	Perm		RecordQualifier	
24	AE	AESCAN	Involves Cancer	24	C	2	text	NY	Perm		RecordQualifier	
25	AE	AESCONG	Congenital Anomaly or Birth Defect	25	C	2	text	NY	Perm		RecordQualifier	
26	AE	AESDISAB	Persist or Signif Disability/Incapacity	26	C	2	text	NY	Perm		RecordQualifier	
27	AE	AESDTH	Results in Death	27	C	2	text	NY	Perm		RecordQualifier	
28	AE	AESHOSP	Requires or Prolongs Hospitalization	28	C	2	text	NY	Perm		RecordQualifier	
29	AE	AESLIFE	Is Life Threatening	29	C	2	text	NY	Perm		RecordQualifier	

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SDTM CLASS METADATA

	SASref	Table	Label	Class	Purpose	Keys
1	REFMETA	EVENTS	Events Observation Class	Events-General	Tabulation	
2	REFMETA	FINDINGS	Findings Observation Class	Findings-General	Tabulation	
3	REFMETA	IDENTIFIERS	Unique Identifiers for All Classes	All Classes	Tabulation	
4	REFMETA	INTERVENTIONS	Interventions Observation Class	Interventions-General	Tabulation	
5	REFMETA	TIMING	Timing Variables for All Classes	All Classes	Tabulation	

	table	column	label	order	type	length	xmldatatype	xmlcodelist	core	role
1	EVENTS	__TERM	Reported Term	1	C	200	text		Req	Topic
2	EVENTS	__MODIFY	Modified Reported Term	2	C	200	text		Perm	SynonymQualifierof__TERM
3	EVENTS	__DECOD	Dictionary-Derived Term	3	C	200	text		Perm	SynonymQualifierof__TERM
4	EVENTS	__CAT	Category	4	C	40	text		Perm	GroupingQualifier
5	EVENTS	__SCAT	Subcategory	5	C	40	text		Perm	GroupingQualifier
6	EVENTS	__PRESP	Pre-specified	6	C	2	text	NY	Perm	RecordQualifier
7	EVENTS	__OCCUR	Occurrence	7	C	2	text	NY	Perm	RecordQualifier
8	EVENTS	__STAT	Completion Status	8	C	40	text	ND	Perm	RecordQualifier
9	EVENTS	__REASND	Reason Not Done	9	C	200	text		Perm	RecordQualifier
10	EVENTS	__BODSYS	Body System or Organ Class	10	C	80	text		Perm	RecordQualifier
11	EVENTS	__LOC	Location of Event	11	C	100	text	LOC	Perm	RecordQualifier
12	EVENTS	__SEV	Severity/Intensity	12	C	20	text		Perm	RecordQualifier
13	EVENTS	__SER	Serious Event	13	C	2	text	NY	Exp	RecordQualifier
14	EVENTS	__ACN	Action Taken with Study Treatment	14	C	40	text	ACN	Exp	RecordQualifier
15	EVENTS	__ACNOTH	Other Action Taken	15	C	200	text		Perm	RecordQualifier

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CONTROLLED TERMINOLOGY

	sourcesystem	sourcesystemv	description	codelist	codelist_code	codelist_name	codelist_extensible	codelist_preferred_term	datatype	type	fmtname	code
1	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	ACN	C66767	Action Taken with Study Treatment	No	CDISC SDTM Action Taken with Study Treatment Terminology	text	C	ACN	C49503
2	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	ACN	C66767	Action Taken with Study Treatment	No	CDISC SDTM Action Taken with Study Treatment Terminology	text	C	ACN	C49504
3	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	ACN	C66767	Action Taken with Study Treatment	No	CDISC SDTM Action Taken with Study Treatment Terminology	text	C	ACN	C49505
4	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	ACN	C66767	Action Taken with Study Treatment	No	CDISC SDTM Action Taken with Study Treatment Terminology	text	C	ACN	C49501
5	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	ACN	C66767	Action Taken with Study Treatment	No	CDISC SDTM Action Taken with Study Treatment Terminology	text	C	ACN	C49502
6	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	ACN	C66767	Action Taken with Study Treatment	No	CDISC SDTM Action Taken with Study Treatment Terminology	text	C	ACN	C48660
7	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	ACN	C66767	Action Taken with Study Treatment	No	CDISC SDTM Action Taken with Study Treatment Terminology	text	C	ACN	C17998
8	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	ACSPCAT	C101865	Acute Coronary Syndrome Presentation Category	No	CDISC SDTM Acute Coronary Syndrome Presentation Category Terminology	text	C	ACSPCAT	C80383
9	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	ACSPCAT	C101865	Acute Coronary Syndrome Presentation Category	No	CDISC SDTM Acute Coronary Syndrome Presentation Category Terminology	text	C	ACSPCAT	C17649
10	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	ACSPCAT	C101865	Acute Coronary Syndrome Presentation Category	No	CDISC SDTM Acute Coronary Syndrome Presentation Category Terminology	text	C	ACSPCAT	C101888
11	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	ACSPCAT	C101865	Acute Coronary Syndrome Presentation Category	No	CDISC SDTM Acute Coronary Syndrome Presentation Category Terminology	text	C	ACSPCAT	C66914
12	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	ACSPCAT	C101865	Acute Coronary Syndrome Presentation Category	No	CDISC SDTM Acute Coronary Syndrome Presentation Category Terminology	text	C	ACSPCAT	C66911
13	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	AESEV	C66769	Severity/Intensity Scale for Adverse Events	No	CDISC SDTM Severity Intensity Scale for Adverse Event Terminology	text	C	AESEV	C41338
14	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	AESEV	C66769	Severity/Intensity Scale for Adverse Events	No	CDISC SDTM Severity Intensity Scale for Adverse Event Terminology	text	C	AESEV	C41339
15	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	AESEV	C66769	Severity/Intensity Scale for Adverse Events	No	CDISC SDTM Severity Intensity Scale for Adverse Event Terminology	text	C	AESEV	C41340
16	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	AGEU	C66781	Age Unit	No	CDISC SDTM Age Unit Terminology	text	C	AGEU	C25301
17	NCI Thesaurus	2013-12-20	CDISC SDTM Controlled Terminology, 2013-12-20	AGEU	C66781	Age Unit	No	CDISC SDTM Age Unit Terminology	text	C	AGEU	C25529

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INTRODUCTION

- Supported with SAS 9.3M2 and 9.4M1 on the following operating systems:
  - Windows x64
  - Linux x64
- Separately orderable component
- Available at no additional charge to currently licensed SAS customers.
- Contact your SAS Account Representative concerning availability

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CREATING THE DEFINE-XML V2 WITH CST

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TYPICAL PROGRAM FLOW

- Define global macro variables ("properties")
  - **%cst_setStandardProperties**

    (_cstStandard=CST-FRAMEWORK,_cstSubType=initialize);
- Define inputs / outputs (libname refs, filename refs, SAS autocall macros, ...)
  1. Create SASReferences dataset
  2. **%cstutil_processsetup();**
- Run process specific macro:
  - **%define_sourcetodefine**
  - **%define_write**
  - **%cstutilxmlvalidate**
  - **%define_read**

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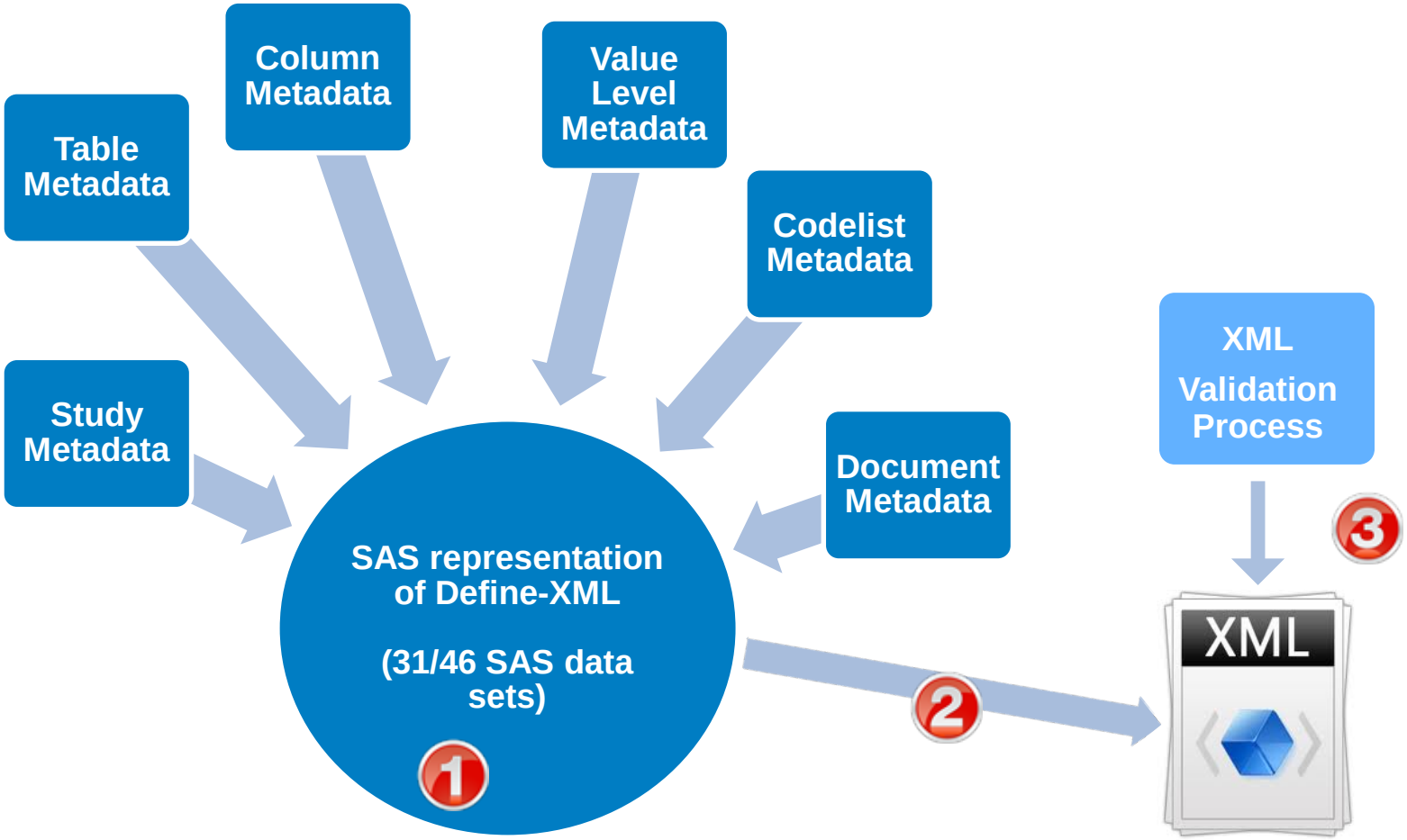
ADAM / SDTM TO DEFINE.XML



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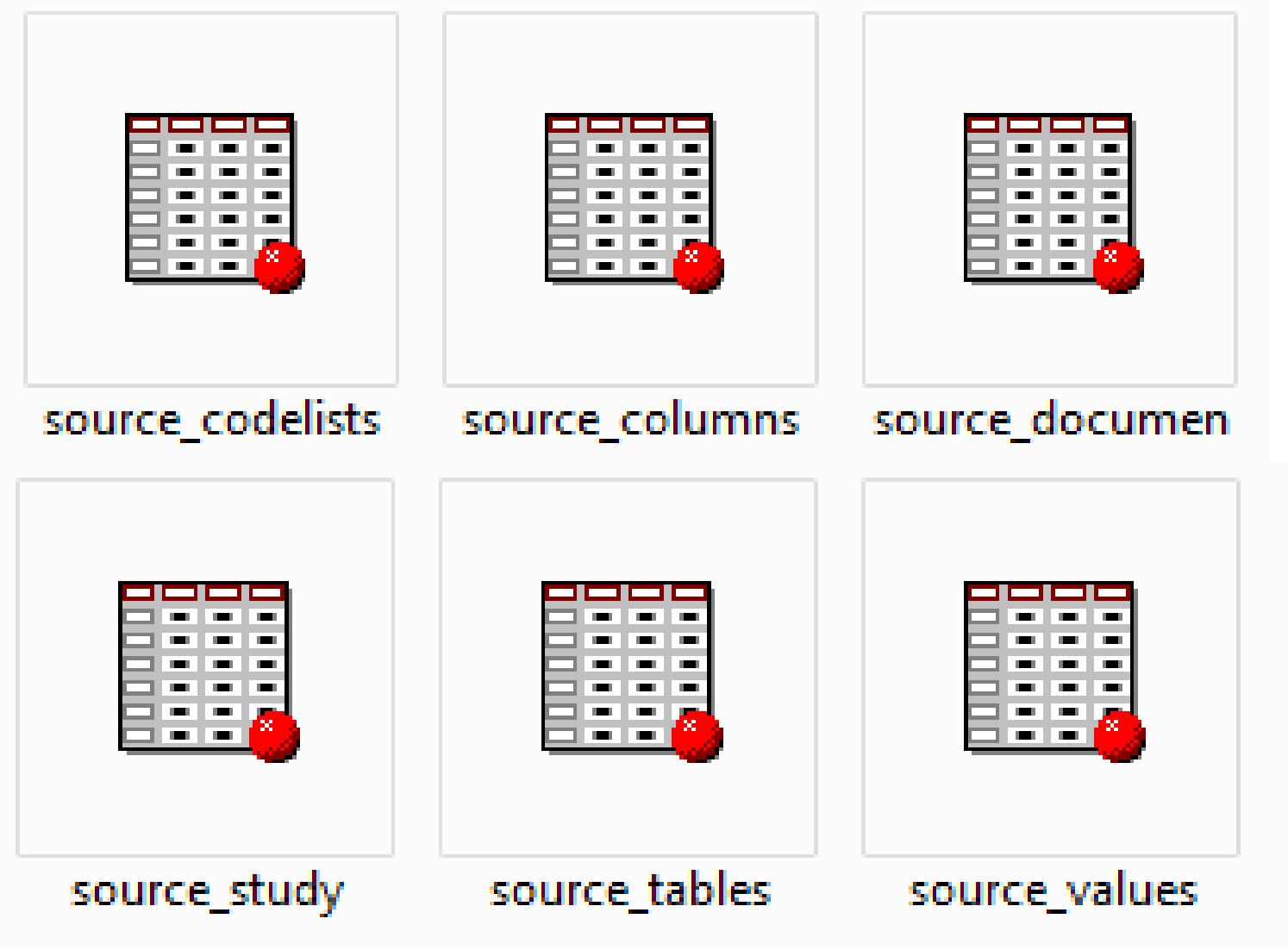
SDTM TO DEFINE.XML



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SOURCE_STUDY

VIEWTABLE: TMP1.source_study (Source Study Metadata)

	STUDYNAME	STUDYDESCRIPTION	PROTOCOLNAME	STUDYVERSION
1	CDISC01	CDISC Test Study	CDISC01	MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2

FORMALSTANDARDNAME	FORMALSTANDARDVERSION
SDTM-IG	3.1.2

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SOURCE_TABLES

VIEWTABLE: TMP2.source_tables (Source Tables Metadata)

	TABLE	LABEL	ORDER	DOMAIN	CLASS	XMLPATH	XMLTITLE
1	TA	Trial Arms	1	TA	TRIAL DESIGN	ta.xpt	ta.xpt
2	TE	Trial Elements	2	TE	TRIAL DESIGN	te.xpt	te.xpt
3	TI	Trial Inclusion/Exclusion Criteria	3	TI	TRIAL DESIGN	ti.xpt	ti.xpt
4	TS	Trial Summary	4	TS	TRIAL DESIGN	ts.xpt	ts.xpt
5	TV	Trial Visits	5	TV	TRIAL DESIGN	tv.xpt	tv.xpt
6	DM	Demographics	6	DM	SPECIAL PURPOSE	dm.xpt	dm.xpt
7	SE	Subject Elements	7	SE	SPECIAL PURPOSE	se.xpt	se.xpt

STRUCTURE	PURPOSE	KEYS	COMMENT
One record per planned Element per Arm	Tabulation	STUDYID ARMCD TAETORD	
One record per planned Element	Tabulation	STUDYID ETCD	
One record per I/E criterion	Tabulation	STUDYID IETESTCD	
One record per trial summary parameter value	Tabulation	STUDYID TSPARMCD TSSEQ	
One record per planned Visit per Arm	Tabulation	STUDYID VISITNUM ARMCD	
One record per subject	Tabulation	STUDYID USUBJID	See Reviewer's Guide, Section 2.1 Demographics
One record per actual Element per subject	Tabulation	STUDYID USUBJID SESTDTC SEENDTC TAETORD ETCD	

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SOURCE_COLUMNS

	TABLE	COLUMN	LABEL	ORDER	TYPE	LENGTH	XMLDATATYPE
1	AE	STUDYID	Study Identifier	1	C	7	text
2	AE	DOMAIN	Domain Abbreviation	2	C	2	text
3	AE	USUBJID	Unique Subject Identifier	3	C	14	text
4	AE	AESEQ	Sequence Number	4	N	1	integer
5	AE	AESPID	Sponsor-Defined Identifier	5	C	4	text
6	AE	AETERM	Reported Term for the Adverse Event	6	C	25	text
7	AE	AEMODIFY	Modified Reported Term	7	C	9	text
8	AE	AEDECOD	Dictionary-Derived Term	8	C	18	text

XMLCODELIST	CORE	ORIGIN	ALGORITHM	STUDYVERSION
	Req	Protocol		MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2
$AEDOM	Req	Assigned		MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2
	Req	Derived	Concatenation of STUDYID and SUBJID	MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2
	Req	Derived	Sequential number identifying records within each USUBJID in the domain.	MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2
	Perm	CRF		MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2
	Req	CRF		MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2
	Perm	Assigned		MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2
$AEDICT	Req	Assigned		MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2

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SOURCE_CODELISTS

	CODELIST	CODELISTNAME	CODELISTNCICODE	CODELISTDATATYPE	SASFORMATNAME
1	CL.ACN	Action Taken with Study Treatment	C66767	text	$ACN
2	CL.ACN	Action Taken with Study Treatment	C66767	text	$ACN
3	CL.ACN	Action Taken with Study Treatment	C66767	text	$ACN
4	CL.ACN	Action Taken with Study Treatment	C66767	text	$ACN
5	CL.AE.DOMAIN	Domain Abbreviation (AE)	C66734	text	$AEDOM
6	CL.AEDICT_F	Adverse Event Dictionary		text	$AEDICT
7	CL.AEENRF	Relation to Reference Period (AEENRF)	C66728	text	$AEENRF
8	CL.AEREL	Causality		text	$AEREL
9	CL.AEREL	Causality		text	$AEREL
10	CL.AEREL	Causality		text	$AEREL

	CODEDVALUECHAR	DECODETEXT	CODEDVALUENCICODE	RANK	ORDERNUMBER	EXTENDEDVALUE	DICTIONARY	VERSION
1	DOSE NOT CHANGED		C49504	.	1			
2	DOSE REDUCED		C49505	.	2			
3	DRUG INTERRUPTED		C49501	.	3			
4	DRUG WITHDRAWN		C49502	.	4			
5	AE	Adverse Events	C49562	.	.			
6				.	.		MEDDRA	8.0
7	AFTER		C38008	.	.			
8	NOT RELATED			.	.			
9	POSSIBLY RELATED			.	.			
10	RELATED			.	.			

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SOURCE_VALUES

	TABLE	COLUMN	WHERECLAUSE	LABEL	ORDER	TYPE	LENGTH	XMLDATATYPE	XMLCODELIS
114	VS	VSORRES	VSTESTCD EQ "DIABP"	Diastolic Blood Pressure (Orig U)	1	N	2	integer	
115	VS	VSORRES	VSTESTCD EQ "FRMSIZE"	Body Frame Size (Orig U)	2	C	6	text	$SIZE
116	VS	VSORRES	VSTESTCD EQ "HEIGHT"	Height (Orig U)	3	N	5	float	
117	VS	VSORRES	VSTESTCD EQ "PULSE"	Pulse Rate (Orig U)	4	N	2	integer	
118	VS	VSORRES	VSTESTCD EQ "SYSBP"	Systolic Blood Pressure (Orig U)	5	N	3	integer	
119	VS	VSORRES	VSTESTCD EQ "WEIGHT"	Weight (Orig U)	6	N	4	float	
120	VS	VSORRESU	VSTESTCD EQ "HEIGHT"	Height: Original Units	1	C	5	text	$UH
121	VS	VSORRESU	VSTESTCD EQ "WEIGHT"	Weight: Original Units	2	C	4	text	$UW

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SOURCE_DOCUMENTS

DOCTYPE	HREF	TITLE	PDFPAGEREFTYPE	PDFPAGEREFS	TABLE	COLUMN	WHERECLAUSE
COMMENT	reviewersguide.pdf	Reviewers Guide	NamedDestination	section2.1	DM		
COMMENT	reviewersguide.pdf	Reviewers Guide			DM	ARMCD	
CRF	blankcrf.pdf	Annotated Case Report Form	PhysicalRef	9 22	CM	CMCAT	
CRF	blankcrf.pdf	Annotated Case Report Form	PhysicalRef	22	CM	CMDOSFRQ	
CRF	blankcrf.pdf	Annotated Case Report Form	PhysicalRef	9 22	CM	CMDOSTXT	
CRF	blankcrf.pdf	Annotated Case Report Form	PhysicalRef	9 22	CM	CMDOSU	
CRF	blankcrf.pdf	Annotated Case Report Form	PhysicalRef	9 22	CM	CMENDTC	
CRF	blankcrf.pdf	Annotated Case Report Form	PhysicalRef	19	DA	DAORRES	
CRF	blankcrf.pdf	Annotated Case Report Form	PhysicalRef	19	DA	DAORRES	DATESTCD EQ "DISPAMT"
CRF	blankcrf.pdf	Annotated Case Report Form	PhysicalRef	19	DA	DAORRES	DATESTCD EQ "RETAMT"
METHOD	complexalgorithms.	Complex Algorithms	NamedDestination	DM	DM	AGE	
METHOD	complexalgorithms.	Complex Algorithms	NamedDestination	EG	EG	EGDRVFL	
METHOD	complexalgorithms.	Complex Algorithms	NamedDestination	EG	EG	EGSTRESC	EGTESTCD EQ "QTCB"
METHOD	complexalgorithms.	Complex Algorithms	NamedDestination	EG	EG	EGSTRESC	EGTESTCD EQ "QTCF"
METHOD	complexalgorithms.	Complex Algorithms	NamedDestination	SE	SE	SEENDTC	
METHOD	complexalgorithms.	Complex Algorithms	NamedDestination	SE	SE	SESTDTC	

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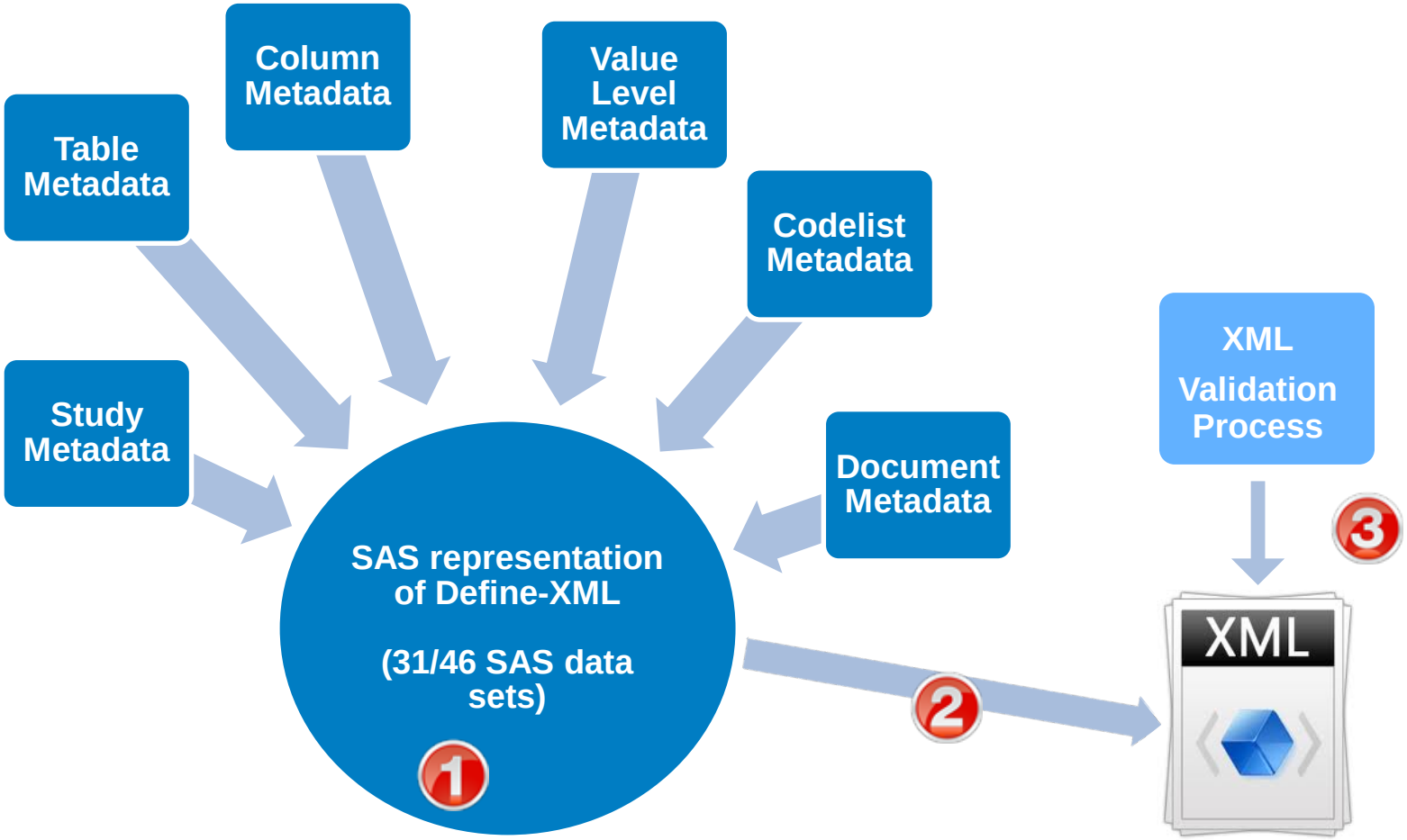
ADAM / SDTM TO DEFINE.XML



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- annotatedcrfs
- mdvleaf
- supplementaldocs
- codelistitems
- definedocument
- formalexpressions
- itemgroupitemrefs
- itemrefwhereclauserefs
- methoddefs
- valuelists
- whereclauserangecheckvalues
- documentrefs
- mdvleaftitles
- translatedtext
- codelists
- enumerateditems
- itemdefs
- itemgroupleaf
- itemvaluelistrefs
- study
- whereclausedefs
- itemorigin
- pdfpagerefs
- aliases
- commentdefs
- externalcodelists
- itemgroupdefs
- itemgroupleaftitles
- metadataversion
- valuelistitemrefs
- whereclauserangechecks

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```
%define_sourcetodefine(
  _cstOutLib=srcdata,
  _cstSourceStudy=sampdata.source_study,
  _cstSourceTables=sampdata.source_tables,
  _cstSourceColumns=sampdata.source_columns,
  _cstSourceCodeLists=sampdata.source_codelists,
  _cstSourceDocuments=sampdata.source_documents,
  _cstSourceValues=sampdata.source_values,
  _cstFullModel=N,
  _cstLang=en
  );

%define_write();

%cstutilxmlvalidate();
```

define.xml
define2-0-0.xsl

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SDTM-IG 3.1.2

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Tabulation Datasets for Study CDISC01 (SDTM-IG 3.1.2)

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
TA	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.xpt	
TE	Trial Elements	TRIAL DESIGN	One record per planned Element	Tabulation	STUDYID, ETCD	te.xpt	
TI	Trial Inclusion/Exclusion Criteria	TRIAL DESIGN	One record per I/E criterion	Tabulation	STUDYID, IETESTCD	ti.xpt	
TS	Trial Summary	TRIAL DESIGN	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ	ts.xpt	
TV	Trial Visits	TRIAL DESIGN	One record per planned Visit per Arm	Tabulation	STUDYID, VISITNUM, ARMCD	tv.xpt	
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt	See Reviewer's Guide, Section 2.1 Demographics Reviewers Guide

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- **DEMO**

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Thank You !

Questions ?

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