



Define.xml tools supporting SEND/SDTM data process

- Using SAS® Clinical Standards Toolkit



PRESENTER / Kirsten Walther Langendorf

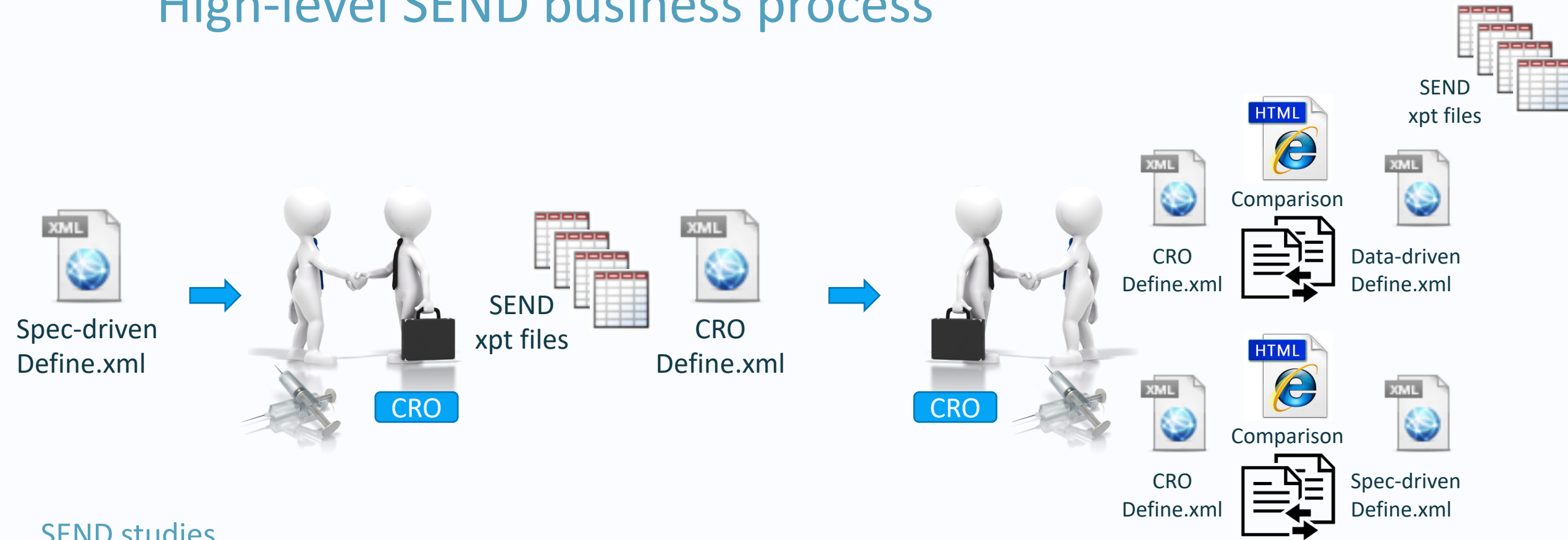
DATE / 11. Oct 2017

OUTLINE



- **Business Process**
High-level SEND process
- **Creating Define.xml**
Spec-driven
Data-driven
Value-level Metadata
Comparing define
- **Managing Standards**
Controlled terminology
Models
- **Conclusion**
Areas of improvement

High-level SEND business process



SEND studies

- Study conduct and data are outsourced
 - Data agreements
- Sponsor must ensure consistency for submission
 - Master model

Creating SEND define.xml

Spec-driven input:

- Provide specification for tables (domains) and columns (variables) in Excel
- Provide subset codelists in Excel
- Provide Value-level Matadata (VLMD), origin and comments/algorithms in Excel (optional)

Data-driven input:

- The xpt data files
- The Value-level Matadata (VLMD), origin and comments/algorithms in Excel (optional)

Spec-driven – model specification

	B	C	D	E	F	G	H	I	
1	table	label	class	xmlpath	xmltitle	structure	purpose	keys	comment
2	BG	Body Weight Gains	Findings	.transport/bg.xpt	Body Weight Gains SAS transport file	One record per test per interval per subject	Tabulation	STUDYID USUBJID BGTESTCD BGDTC BGENDTC	Body weight gain is the act
3	BW	Body Weights	Findings	.transport/bw.xpt	Body Weights SAS transport file	One record per test per observation time per subject	Tabulation	STUDYID USUBJID BWTESTCD BWDTC	This domain captures body
4	CL	Clinical Observations	Findings	.transport/cl.xpt	Clinical Observations SAS transport file	One record per finding per observation time per subject or pool	Tabulation	STUDYID USUBJID CLTESTCD CLCAT CLORRES CLLOC CLDTC	This domain captures clinic
5	CO	Comments	Special Purpose Domains	.transport/co.xpt	Comments SAS transport file	One record per comment	Tabulation	STUDYID COSEQ	The Comments special-pur
6	DS	Disposition	Events	.transport/ds.xpt	Disposition SAS transport file	One record per subject	Tabulation	STUDYID USUBJID	The disposition dataset por
7	EX	Exposure	Interventions	.transport/ex.xpt	Exposure SAS transport file	One record per constant dosing interval per treatment per subject or pool	Tabulation	STUDYID USUBJID EXTRT EXSTDTC	The Exposure Domain Moc
8	LB	Laboratory Tests Results	Findings	.transport/lb.xpt	Laboratory Tests Results SAS transport file	One record per test per specimen per observation time per subject or pool	Tabulation	STUDYID USUBJID LBTESTCD LBSPEC LBDTC LBTPTNJM	This domain captures labor
9	MA	Macroscopic Findings	Findings	.transport/ma.xpt	Macroscopic Findings SAS transport file	One record per finding per specimen per subject	Tabulation	STUDYID USUBJID MATESTCD MAORRES MASPEC MAANTREG MALAT MADIR	The macroscopic findings i
10	MI	Microscopic Findings	Findings	.transport/mi.xpt	Microscopic Findings SAS transport file	One record per finding per specimen per subject	Tabulation	STUDYID USUBJID MITESTCD MISTRES MISPEC MANTREG MILAT MIDIR	This domain captures the n
11	OM	Organ Measurements	Findings	.transport/om.xpt	Organ Measurements SAS transport file	One record per test per specimen per subject	Tabulation	STUDYID USUBJID OMTESTCD OMSPEC OMANTREG OMLAT OMDIR	The Organ Measurements I
12	RELREC	Related Records	Relationship Datasets	.transport/relec.xpt	Related Records SAS transport file	One record per related record, related group of records (e.g., -GRPID), or related data	Tabulation	STUDYID RDOMAIN USUBJID IDVAR IDVARVAL RELID	This domain represents rel.
13	SUPPBG	Supplemental Qualifiers	Relationship Datasets	.transport/suppbg.xpt	Supplemental Qualifiers SAS transport file	One record per IDVAR, IDVARVAL, and QNAM value per subject per related domain	Tabulation	STUDYID RDOMAIN USUBJID IDVAR IDVARVAL QNAM	The Supplemental Qualifie
14	SUPPBW	Supplemental Qualifiers	Relationship Datasets	.transport/suppbw.xpt	Supplemental Qualifiers SAS transport file	One record per IDVAR, IDVARVAL, and QNAM value per subject per related domain	Tabulation	STUDYID RDOMAIN USUBJID IDVAR IDVARVAL QNAM	The Supplemental Qualifie
15	SUPPCL	Supplemental Qualifiers	Relationship Datasets	.transport/suppcl.xpt	Supplemental Qualifiers SAS transport file	One record per IDVAR, IDVARVAL, and QNAM value per subject per related domain	Tabulation	STUDYID RDOMAIN USUBJID IDVAR IDVARVAL QNAM	The Supplemental Qualifie
16	SUPPDS	Supplemental Qualifiers	Relationship Datasets	.transport/suppds.xpt	Supplemental Qualifiers SAS transport file	One record per IDVAR, IDVARVAL, and QNAM value per subject per related domain	Tabulation	STUDYID RDOMAIN USUBJID IDVAR IDVARVAL QNAM	The Supplemental Qualifie
17	SUPPLB	Supplemental Qualifiers	Relationship Datasets	.transport/supplb.xpt	Supplemental Qualifiers SAS transport file	One record per IDVAR, IDVARVAL, and QNAM value per subject per related domain	Tabulation	STUDYID RDOMAIN USUBJID IDVAR IDVARVAL QNAM	The Supplemental Qualifie
18	SUPPMA	Supplemental Qualifiers	Relationship Datasets	.transport/suppma.xpt	Supplemental Qualifiers SAS transport file	One record per IDVAR, IDVARVAL, and QNAM value per subject per related domain	Tabulation	STUDYID RDOMAIN USUBJID IDVAR IDVARVAL QNAM	The Supplemental Qualifie
19	SUPPMI	Supplemental Qualifiers	Relationship Datasets	.transport/suppmi.xpt	Supplemental Qualifiers SAS transport file	One record per IDVAR, IDVARVAL, and QNAM value per subject per related domain	Tabulation	STUDYID RDOMAIN USUBJID IDVAR IDVARVAL QNAM	The Supplemental Qualifie
20	SUPPVS	Supplemental Qualifiers	Relationship Datasets	.transport/suppvs.xpt	Supplemental Qualifiers SAS transport file	One record per IDVAR, IDVARVAL, and QNAM value per subject per related domain	Tabulation	STUDYID RDOMAIN USUBJID IDVAR IDVARVAL QNAM	The Supplemental Qualifie
21	VS	Vital Signs	Findings	.transport/vs.xpt	Vital Signs SAS transport file	One record per measurement per observation time per subject	Tabulation	STUDYID USUBJID VSTESTCD VSDTC	This domain is intended to
22									

	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	
1	table	column	label	ordr	typ	lengl	displayform	xmldatatype	xmlcodeis	cor	origin	role	term	algorithm	qualifiers	comment
2	BG	STUDYID	Study Identifier	1	C	6		text		Req		Identifier				Unique identifier for a study.
3	BG	DOMAIN	Domain Abbreviation	2	C	2		text		Req		Identifier	BG		UPPERCASE	Two-character abbreviation for the domain.
4	BG	USUBJID	Unique Subject Identifier	3	C	11		text		Req		Identifier				Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
5	BG	BGSEQ	Sequence Number	4	N	8		integer		Req		Identifier				Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
6	BG	BGTESTCD	Test Short Name	5	C	6		text	BGTESTCD	Req		Topic	(BGTESTCD)		UPPERCASE	Short name of the measurement, test, or examination described in BGTEST. It can be used as a column name when conv
7	BG	BGTEST	Test Name	6	C	16		text	BGTEST	Req		SynonymQualifier	(BGTEST)			Long name for BGTESTCD. The value in BGTEST cannot be longer than 40 characters.
8	BG	BGORRES	Result or Findings as Collected	7	C	5		text		Exp		ResultQualifier				Result of the measurement or finding as originally recorded.
9	BG	BGORRESU	Unit of the Original Result	8	C	2		text	UNIT	Exp		VariableQualifier	(UNIT)			The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Te
10	BG	BGSTRESC	Standardized Result in Character Format	9	C	5		text		Exp		ResultQualifier				Contains the result value for all findings or derived from BGORRES in a standard format or standard units. BGSTRESC sh
11	BG	BGSTRESN	Standardized Result in Numeric Format	10	N	8 8.3		float		Exp		ResultQualifier				Used for results or findings in standard format; contains the numeric form of BGSTRESC. BGSTRESN should store all nu
12	BG	BGSTRESU	Unit of the Standardized Result	11	C	2		text	UNIT	Exp		VariableQualifier	(UNIT)			Standardized unit used for BGSTRESC or BGSTRESN.
13	BG	BGDTC	Date/Time Animal Weighed	16	C	64		datetime		Exp		Timing	ISO8601		DATE TIME	Datetime of the start of the weight interval in ISO 8601 format. This must be populated when BGTESTCD is BWGAINA.
14	BG	BGENDTC	End Date/Time Animal Weighed	17	C	64		datetime		Exp		Timing	ISO8601		DATE TIME	Datetime of the end of the weight interval in ISO 8601 format. This must be populated when BGTESTCD is BWGAINA.
15	BG	BGDY	Study Day Animal Weighed	18	N	8		integer		Perm		Timing				Study day of the start of the weight interval, in integer days. The algorithm for calculations must be relative to the sponsor-
16	BG	BGENDY	Study Day of End of Weight Interval	19	N	8		integer		Perm		Timing				Study day of the end of the weight interval, in integer days. The algorithm for calculations must be relative to the sponsor-
17	BW	STUDYID	Study Identifier	1	C	6		text		Req		Identifier				Unique identifier for a study.
18	BW	DOMAIN	Domain Abbreviation	2	C	2		text		Req		Identifier	BW		UPPERCASE	Two-character abbreviation for the domain.
19	BW	USUBJID	Unique Subject Identifier	3	C	11		text		Req		Identifier				Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
20	BW	BWSEQ	Sequence Number	4	N	8		integer		Req		Identifier				Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
21	BW	BWTESTCD	Test Short Name	5	C	6		text	BWTESTCD	Req		Topic	(BWTESTCD)		UPPERCASE	Short name of the measurement, test, or examination described in BWTEST. It can be used as a column name when conv
22	BW	BWTEST	Test Name	6	C	20		text	BWTEST	Req		SynonymQualifier	(BWTEST)			Long name for BWTESTCD. The value in BWTEST cannot be longer than 40 characters.
23	BW	BWORRES	Result or Findings as Collected	7	C	4		text		Exp		ResultQualifier				Result of the measurement or finding as originally received or collected.
24	BW	BWORRESU	Unit of the Original Result	8	C	2		text	UNIT	Exp		VariableQualifier	(UNIT)			The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Te
25	BW	BWSTRESC	Standardized Result in Character Format	9	C	4		text		Exp		ResultQualifier				Contains the result value for all findings or derived from BWORRES in a standard format or standard units. BWSTRESC s
26	BW	BWSTRESN	Standardized Result in Numeric Format	10	N	8 8.3		float		Exp		ResultQualifier				Used for results or findings in standard format; contains the numeric form of BWSTRESC. BWSTRESN should store all
27	BW	BWSTRESU	Unit of the Standardized Result	11	C	2		text	UNIT	Exp		VariableQualifier	(UNIT)			Standardized unit used for BWSTRESC or BWSTRESN.

Spec-driven – Study Specific controlled terminology

A	C	D	E	F	G	H	I	N	O
sourcesystem	description	codelist	codelist	codelist_name	codelist_extensible	codelist_synonym	codelist	code	cdisc_submission_value
NCI Thesaurus	CDISC SEND Controlled Terminology, 2014-06-27	COUNTRY	C66786	Country	No	Country	A collectiv	C16496	DNK
NCI Thesaurus	CDISC SEND Controlled Terminology, 2014-06-27	COUNTRY	C66786	Country	No	Country	A collectiv	C16592	FRA
NCI Thesaurus	CDISC SEND Controlled Terminology, 2014-06-27	COUNTRY	C66786	Country	No	Country	A collectiv	C16636	DEU
NCI Thesaurus	CDISC SEND Controlled Terminology, 2014-06-27	COUNTRY	C66786	Country	No	Country	A collectiv	C17180	SWE
NCI Thesaurus	CDISC SEND Controlled Terminology, 2014-06-27	COUNTRY	C66786	Country	No	Country	A collectiv	C17181	CHE
NCI Thesaurus	CDISC SEND Controlled Terminology, 2014-06-27	COUNTRY	C66786	Country	No	Country	A collectiv	C17233	GBR
NCI Thesaurus	CDISC SEND Controlled Terminology, 2014-06-27	COUNTRY	C66786	Country	No	Country	A collectiv	C17234	USA

Examples of study-specific terminology :

- Lab tests being used
- PK parameters
- Body weight

If CT not on study-specific list then define.xml will use master codelist in SAS Clinical Standards Toolkit

Executing the macro

SAS program

- `*includes the standard parameters;`
- `%include "%program_path_v01()\..\..\study_parms.sas";`
-
- `*executes the create-define_v01_spec;`
- `%create_define_v01_spec;`

Output

SEND-IG 3.0							
Date of document generation: 2016-09-22T15:26:03+02:00							
Stylesheet version: 2014-09-03							
Tabulation Datasets for Study 117002 (SEND-IG 3.0)							
Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
BG	Body Weight Gains	FINDINGS	One record per test per interval per subject	Tabulation	STUDYID, USUBJID, BGTESTCD, BGDTC, BGENDTC	Body Weight Gains transport file	See Study Data Reviewers Guide, Section 1 Study Data Reviewers Guide
BW	Body Weights	FINDINGS	One record per test per observation time per subject	Tabulation	STUDYID, USUBJID, BWTESTCD, BWDTC	Body Weights transport file	
CL	Clinical Observations	FINDINGS	One record per finding per observation time per subject or pool	Tabulation	STUDYID, USUBJID, CLTESTCD, CLCAT, CLORRES, CLLOC, CLDTC	Clinical Observations transport file	
CO	Comments	SPECIAL PURPOSE DOMAINS	One record per comment	Tabulation	STUDYID, COSEQ	Comments transport file	
DS	Disposition	EVENTS	One record per subject	Tabulation	STUDYID, USUBJID	Disposition transport file	
EX	Exposure	INTERVENTIONS	One record per constant dosing interval per treatment per subject or pool	Tabulation	STUDYID, USUBJID, EXTRT, EXSTDTC	Exposure transport file	
LB	Laboratory Tests Results	FINDINGS	One record per test per specimen per observation time per subject or pool	Tabulation	STUDYID, USUBJID, LBTESTCD, LBSPEC, LBDTC	Laboratory Tests Results transport file	

Data-driven define.xml

SAS Clinical Standards Toolkit
(CST) metadata for define.xml

-  BG
-  BW
-  CL
-  CO
-  DM
-  DS
-  EX
-  FW
-  LB
-  MA
-  MI
-  OM
-  RELREC
-  SE
-  SUPPLB
-  SUPPMA
-  SUPPMI
-  TA
-  TE
-  TS
-  TX

ValueLevelMetaData

[illegible]

- source_codelists
- source_columns
- source_documents
- source_study
- source_tables
- source_values

...used as input for the define.xml generation in SAS CST

...more user-entered metadata for define.xml

Source Codelists

Enter your data in coloured area below													
Unique Identifier for this CodeList	CodeList Name	CodeList Description	CodeList NCI Code	CodeList item value data type (integer float text string)	SAS format name	Value of the codelist item (character)	Value of the codelist item (numeric)	Decode value of the codelist item	Language	CodeList Item NCI Code	CodedValue order relative to other item values	Display order of the item within the CodeList.	Coded value that has been used to extend external controlled terminology
codelist	codelistname	codelistdescrip	codelistncicode	codelistdatatype	sasformatname	codedvaluechar	codedvaluenu	decodetext	decodelanguage	codedvaluencicode	rank	ordernumber	extendedvalue
CL.BGUNIT	Units (permissible) for Body Weight Gain (BG)		C71620	text	\$UNIT	g							
CL.BGUNIT	Units (permissible) for Body Weight Gain (BG)		C71620	text	\$UNIT	kg							
CL.BGSUNIT	Unit (standard) for Body Weight Gain (BG)		C71620	text	\$UNIT	g							
CL.SPEC	Specimen		C77529	text	\$SPEC	LYMPH NODE, SUBMANDIBULAR							Yes

Source Values

[illegible]

Data-driven define.xml

BG
BW
CL
CO
DM
DS
EX
FW
LB
MA
MI
OM
RELREC
SE
SUPPLB
SUPPMA
SUPPMI
TA
TE
TS
TX
ValueLevelMetaData

source_codelists
source_columns
source_documents
source_study
source_tables
source_values

Study : from `study_parms.sas` (Study ID, Title, SEND version)
Tables : as data + VLMD(Comments)
Columns : as data + VLMD(Comments/Algorithms/Origin)
Code lists : as data + VLMD (extended values)
Values and documents : VLMD

aliases
codelists
defineddocument
externalcodelists
formdefs
itemdefs
itemgroupleaf
itemorigin
itemrangecheckvalues
itemvaluelistrefs
measurementunits
pdfpagerefs
study
supplementaldocs
valuelists
whereclauserangecheckvalues
annotatedcrfs
commentdefs
documentrefs
formalexpressions
formitemgrouprefs
itemgroupdefs
itemgroupleaftitles
itemquestionexternal
itemrefwhereclauserefs
mdvleaf
metadataaversion
presentation
studyeventdefs
translatedtext
whereclausedefs
codelistitems
conditiondefs
enumerateditems
formarchlayouts
imputationmethods
itemgroupitemrefs
itemmurefs
itemrangechecks
itemrole
mdvleaftitles
methoddefs
protocoleventrefs
studyeventformrefs
valuelistitemrefs
whereclauserangechecks

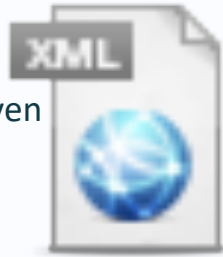


The following code(s) were not valid

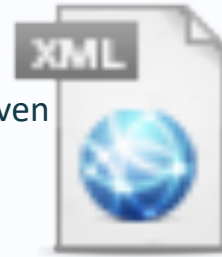
Obs	cdisc_submission_value
1	LYMPH NODE, SUBMANDIBULAR

Compare define.xml

BASE – e.g. Spec-driven



COMP – e.g. Data-driven



`%define_read();`

`define.map (xml <-> SAS)`

- aliases
- codelists
- definedocument
- externalcodelists
- formdefs
- itemdefs
- itemgroupleaf
- itemorigin
- itemrangecheckvalues
- itemvaluelistrefs
- measurementunits
- pdfpagerefs
- study
- supplementaldocs
- valuelists
- whereclauserangecheckvalues

- annotatedcrfs
- commentdefs
- documentrefs
- formaleexpressions
- formitemgrouprefs
- itemgroupdefs
- itemgroupleaftitles
- itemquestionexternal
- itemrefwhereclauserefs
- mdvleaf
- metadataaversion
- presentation
- studyeventdefs
- translatedtext
- whereclauserefs

- codelistitems
- conditiondefs
- enumerateditems
- formarchlayouts
- imputationmethods
- itemgroupitemrefs
- itemmurefs
- itemrangechecks
- itemrole
- mdvleaftitles
- methoddefs
- protocoleventrefs
- studyeventformrefs
- valuelistitemrefs
- whereclauserangechecks

Comparing using PROC SQL and DATA steps

(B) BASELIB: \\FSDKHQ001\\x\$SENDProject\\IT system\\SAS Implementation\\Study\\10_SAS\\03_Define\\01_Spec_driven\\02_output\\spec_define_new_STANDARD_STANDARD_2016-09-22T15-23.xml
(C) COMPLIB: \\FSDKHQ001\\x\$SENDProject\\IT system\\SAS Implementation\\Study\\10_SAS\\03_Define\\02_data_driven\\02_output\\del1c_data_define_2016-11-25T12-14.xml

COMPARING ODM attributes

COMPARED_VARIABLE	BASELIB_VALUE	COMPLIB_VALUE	status
ODM_FILE_TYPE	Snapshot	Snapshot	OK

COMPARED_VARIABLE	BASELIB_VALUE	COMPLIB_VALUE	status
ODM_ODMVERSIONSPEC	Snapshot	Snapshot	OK

STUDY COMPARISON

COMPARED_VARIABLE	BASELIB_VALUE	COMPLIB_VALUE	status
OID	STUDY1	STUDY1	OK
StudyName	117002	216127	NOT OK
ProtocolName	Tox evaluation of drug ██████████ 117002	Tox evaluation of drug ██████████ 0765	NOT OK
StudyDescription	Specification 117002CRO	Specification 216127	NOT OK

METADATAVERSION COMPARISON

COMPARED_VARIABLE	BASELIB_VALUE	COMPLIB_VALUE	status
OID	1.0	1.0	OK
NAME	Metadata for 117002, SEND-IG 3.0	Metadata for 216127, SEND-IG 3.0	NOT OK
DefineVersion	2.0.0	2.0.0	OK

Compare define.xml

ITEMGROUPDEF COMPARISON		
BASECNTOID	COMPCNTOID	status
20	5	NOT OK MISSMATCH IN COUNTS

B.OID	STATUS
IG.BG	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.BW	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.CL	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.CO	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.DS	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.EX	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.LB	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.MA	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.MI	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.OM	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.RELREC	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.SUPPBG	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.SUPPBW	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.SUPPCL	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.SUPPDS	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.SUPPLB	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.SUPPMA	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.SUPPMI	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.SUPPVS	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB
IG.VS	NOT OK CORRESPONDING OID CANNOT BE FOUND IN COMPLIB

C.OID	STATUS
IG.DM	NOT OK CORRESPONDING OID CANNOT BE FOUND IN BASELIB
IG.TA	NOT OK CORRESPONDING OID CANNOT BE FOUND IN BASELIB
IG.TE	NOT OK CORRESPONDING OID CANNOT BE FOUND IN BASELIB
IG.TS	NOT OK CORRESPONDING OID CANNOT BE FOUND IN BASELIB
IG.TX	NOT OK CORRESPONDING OID CANNOT BE FOUND IN BASELIB

Table compared	Variables compared
Study	OID Studyname Protocolname StudyDescription
Metadataversion	OID Name DefineVersion
ItemGroupDefs	OID Name Repeating TranslatedText Class
ValueListItemRefs	OID ItemOID OrderNumber Mandatory
ItemDefs	OID Name DataType Length Comment TranslatedText
Codelists	OID Name DataType
CodelistItems	CodedValue
TranslatedText	See description below
Valuelists	OID
ValueListItemRefs	

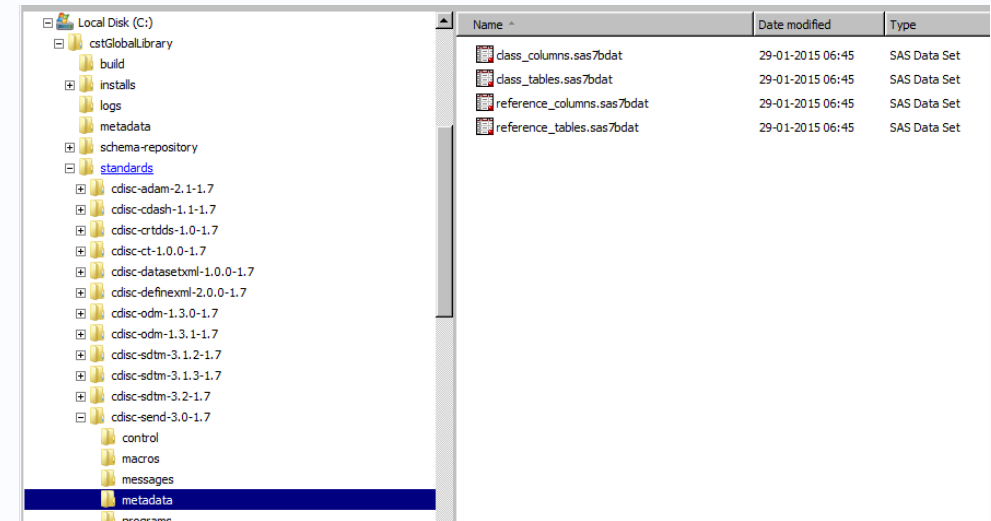
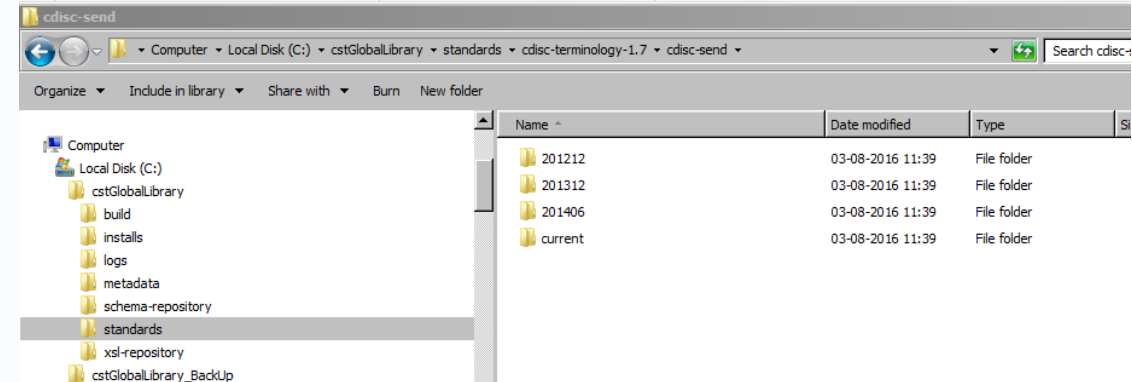
Managing standards

Controlled terminology:

- Macro that registers odm.xml file, downloaded from NCI, into the cstGlobalLibrary

Data Model (SEND):

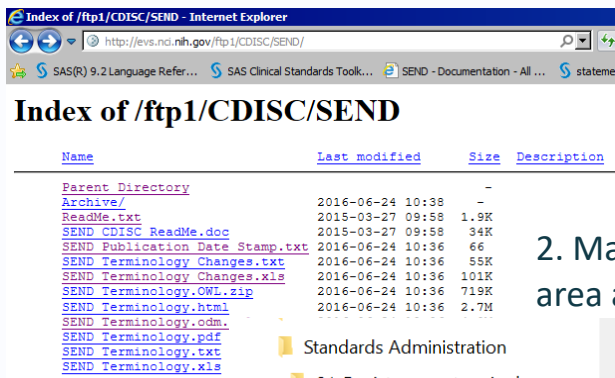
- Macro to create new model in cstGlobalLibrary
- Macro to un-register model in cstGlobalLibrary



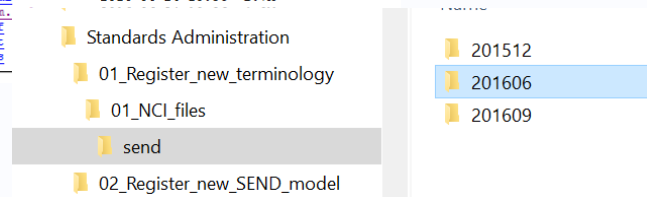
Steps in registering new terminology

Terminology in cstGlobal Library

1. Download terminology

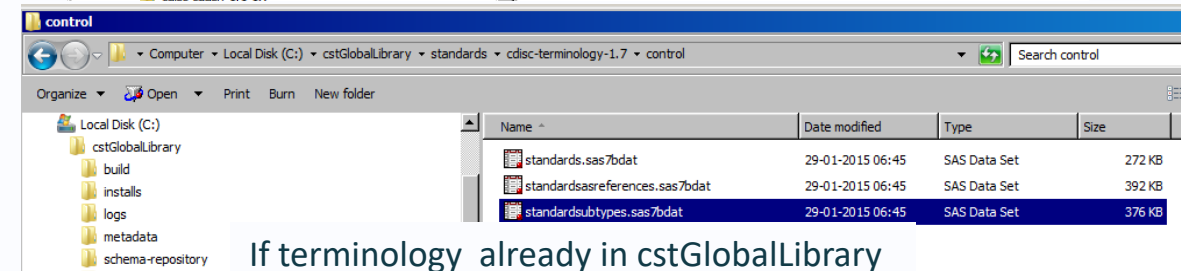
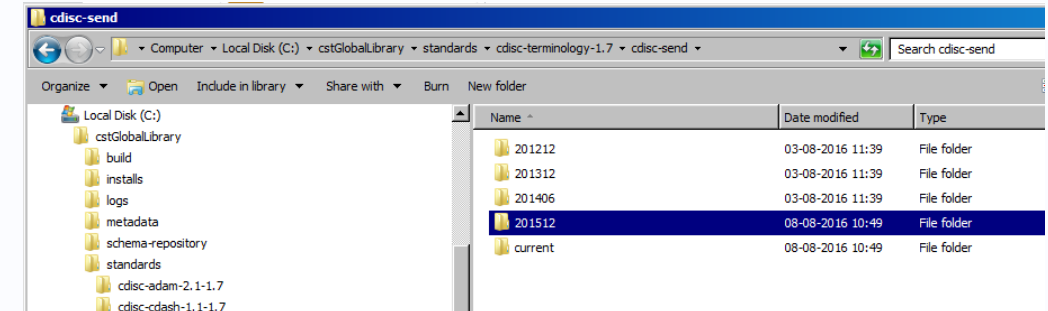


2. Make folder for it in Standards Admin area and store it



3. Run macro

```
31  
32 %include "%program_path_v01()..\init_parms.sas";  
33  
34 *The macro register_new_version_ct_v01;  
35  
36 %register_new_version_ct_v01(CTFile=SEND_Terminology.odm,  
37                             CTDate=201512,  
38                             CTDescription=CDISC SEND Controlled Terminology released by NCI on 2015-1  
39                             DEFAULT_STD=Y);  
40
```



If terminology already in cstGlobalLibrary

ERROR: The Controlled Terminology from 201512 is already in the CST Global library
If you want to redo the process then delete the folder
(C:\cstGlobalLibrary\standards\cdisc-terminology-1.7\cdisc-send\201512\)
in CST Global Library and then run mk_register_new_version_ct program again

USER_INPUT
Command ==>

The Controlled Terminology from 201512 is already in the CST Library. Do you want to unregister it (Y/N):

Conclusion

When **using SAS and being familiar with programming**, the SAS Clinical Standards Toolkit provides a **flexible and efficient** way of managing the SEND (SDTM) model, controlled terminology and generating define.xml.

The macros described have been developed to fit customer needs and business process.

Improvements:

- The **VLMD** provided in the excel-sheet could be **created automatically**, e.g. adding sponsor-defined codes to the code list
- The model specification could be extended to include more columns **providing VLMD on a master model level**
- The **define.xml comparison** report could be based on **the source metadata** datasets and not the xml-like datasets. The source metadata datasets are typically more familiar to the user due to the structure of the VLMD input file.
- The **UI** used is based on the %WINDOWS and %DISPLAY commands in SAS. To make the interface more up to date a **web-based interface** could be developed using SAS stored processes. Using this approach would also free the user from executing the SAS macros.

Thank you

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