

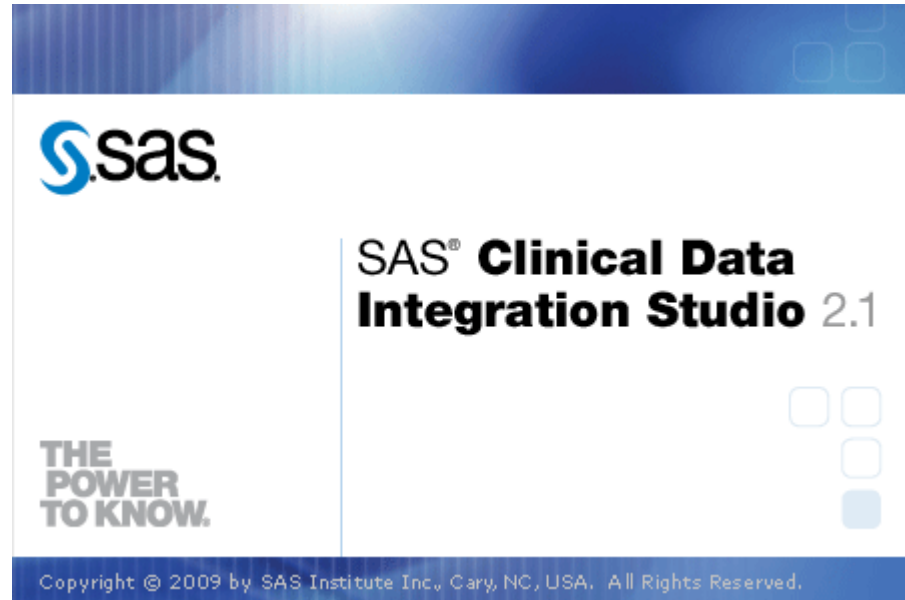
Using SAS[®] Clinical Data Integration to Implement and Manage CDISC Standards

**THE
POWER
TO KNOW[®]**

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SAS[®] Clinical Data Integration

- New product offering from SAS
- Available for SAS 9.2 Platform
- Extends functionality of SAS[®] Data Integration Studio
 - Plug-ins
 - Transformations
 - Reports



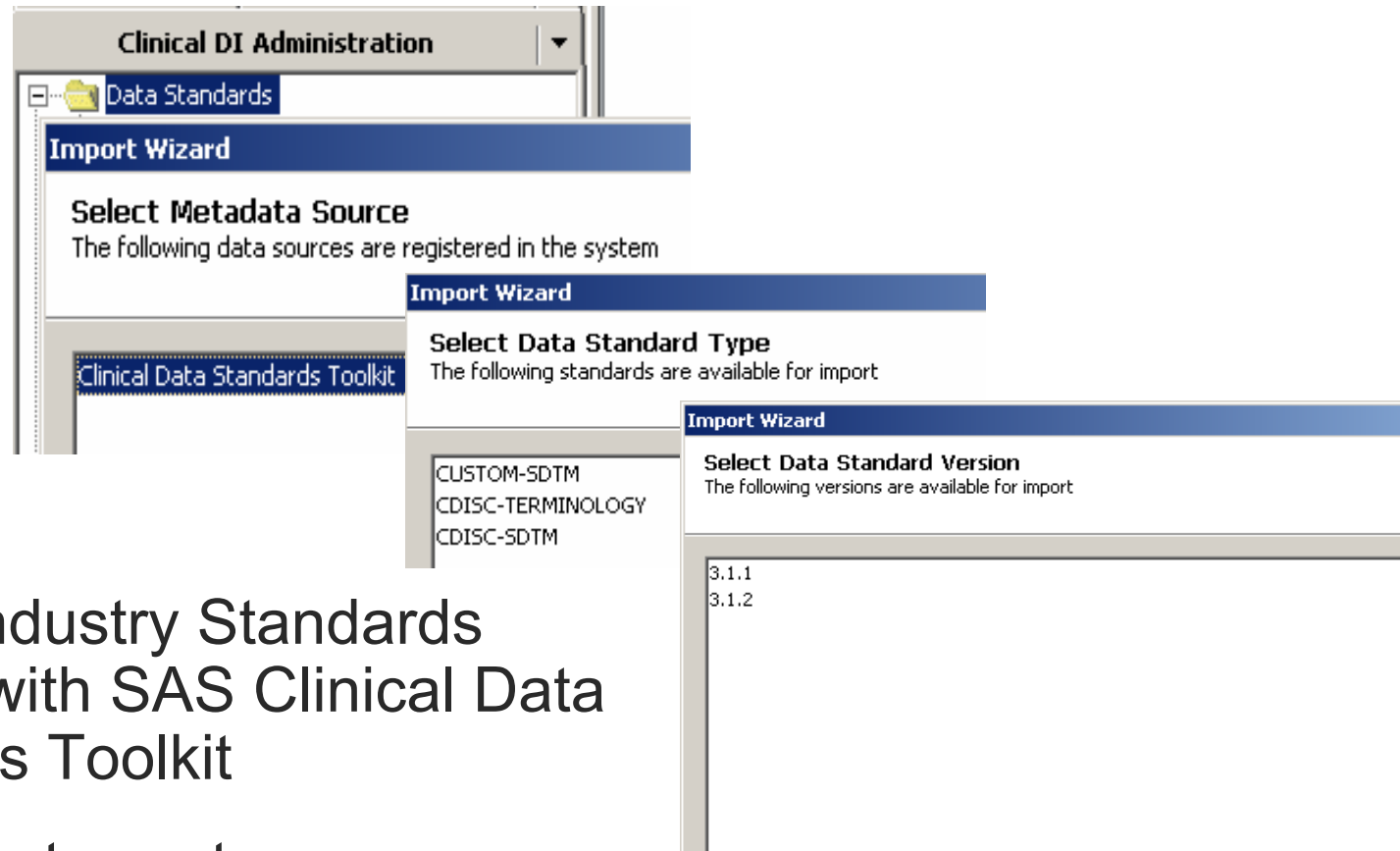
SAS Clinical Data Integration Features

- Provides a central platform for metadata management of industry standards
- Flexible for CDISC +/- scenarios and custom standards
- Customized Data Integration Plug-ins for Standards Management
- Customized Transformations for Standards validation and Define.xml generation
- Integrates with SAS[®] Clinical Standards Toolkit for validation and conversion between models

SAS Clinical Data Integration Workflow

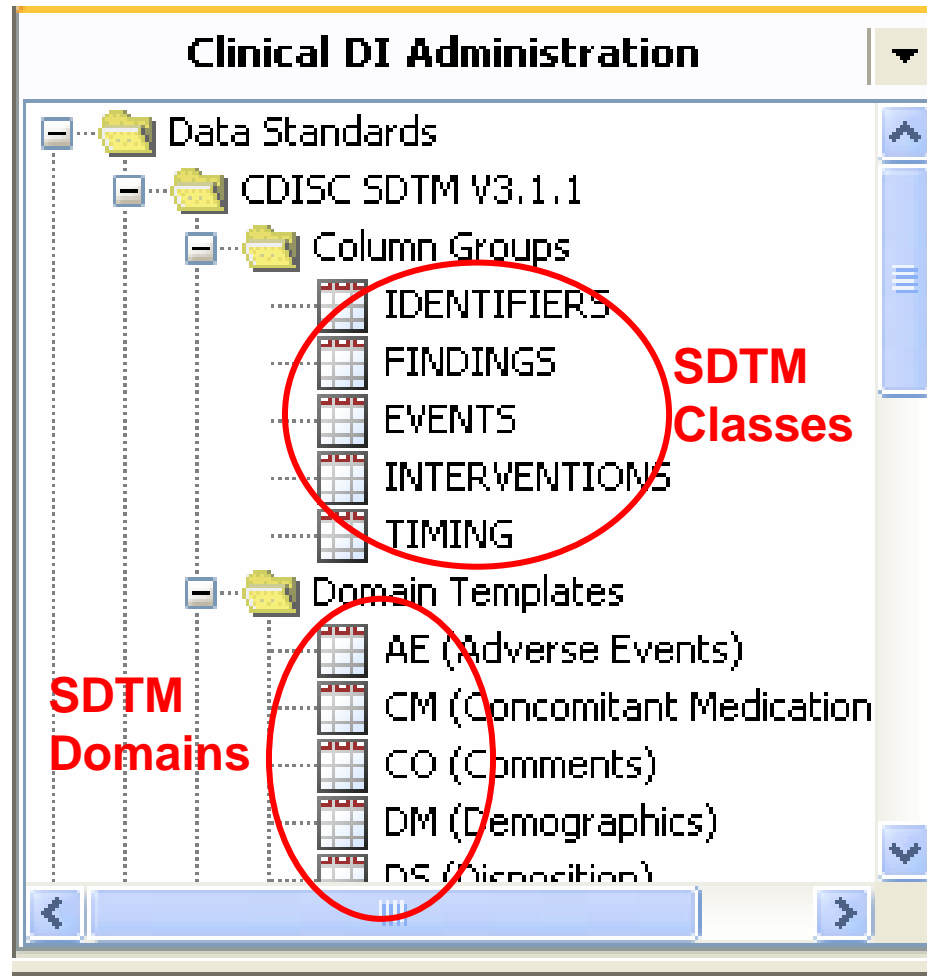
- Import Data Standards
- Customizing Data Standards
- Configuration of Defaults
- Create a Clinical Component
- Define Domains
- Utilize Metadata in transformation process
- Monitor Development Status
- Analyze Use of Data Standard

Importing Data Standards



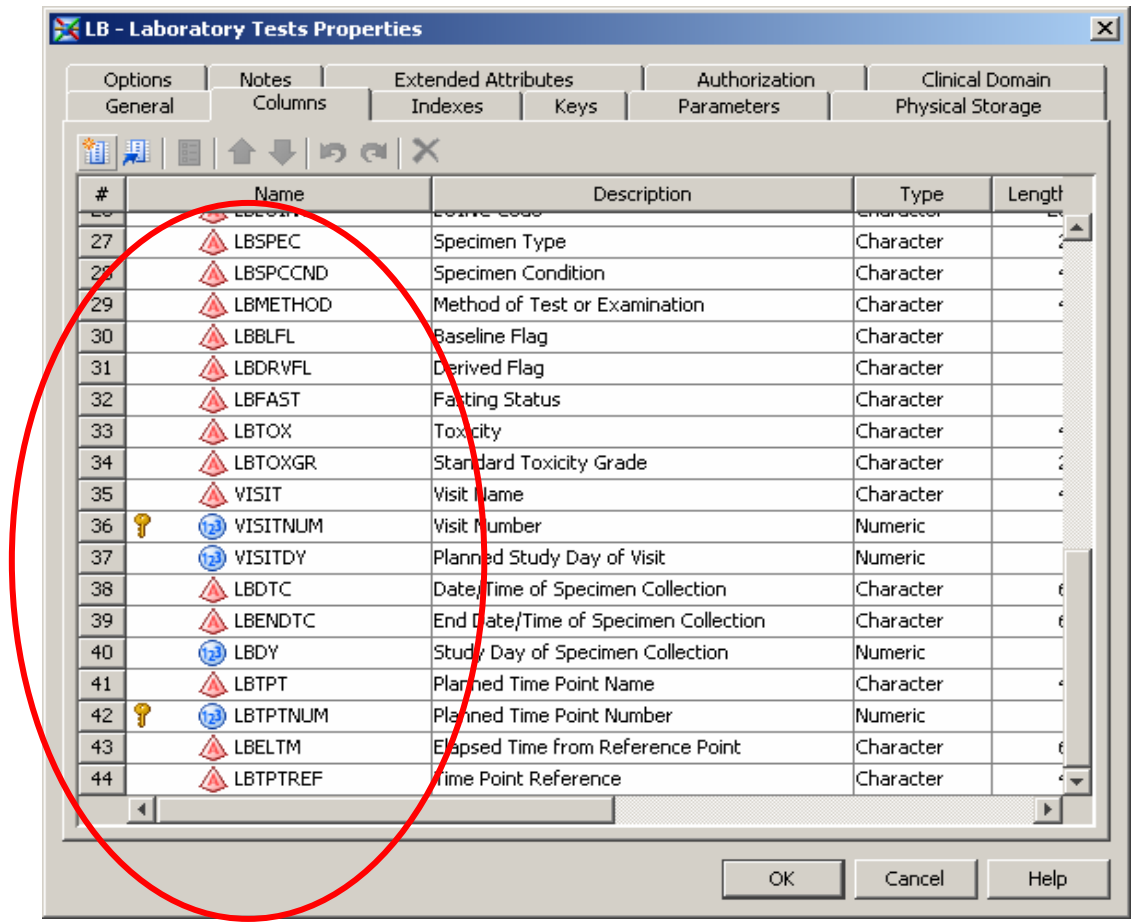
- CDISC Industry Standards shipped with SAS Clinical Data Standards Toolkit
- Adaptable to custom implementations
 - SDTM +/-
 - Internal Standards

Data Standard Loaded in Metadata



Customizing Data Standards

- SDTM Standard LB Domain



#	Name	Description	Type	Length
27	LBSPEC	Specimen Type	Character	2
28	LBSPECND	Specimen Condition	Character	6
29	LBMETHOD	Method of Test or Examination	Character	6
30	LBSPECFL	Baseline Flag	Character	1
31	LBDRVFL	Derived Flag	Character	1
32	LBFAS	Fasting Status	Character	1
33	LBTX	Toxicity	Character	6
34	LBTXGR	Standard Toxicity Grade	Character	2
35	VISIT	Visit Name	Character	6
36	VISITNUM	Visit Number	Numeric	6
37	VISITDY	Planned Study Day of Visit	Numeric	6
38	LBDTC	Date/Time of Specimen Collection	Character	6
39	LBENDTC	End Date/Time of Specimen Collection	Character	6
40	LBDY	Study Day of Specimen Collection	Numeric	6
41	LBTPT	Planned Time Point Name	Character	6
42	LBTPTNUM	Planned Time Point Number	Numeric	6
43	LBELTM	Elapsed Time from Reference Point	Character	6
44	LBTPTREF	Time Point Reference	Character	6

Customizing Data Standards

- Customized LB Domain (SDTM +/-)

LB - Laboratory Tests Properties

Physical Storage | Options | Notes | Extended Attributes | Authorization | Clinical Domain

General | Columns | Indexes | Keys | Parameters

#	Name	Description	Type	Length	Informat	Form
1	STUDYID	Study Identifier	Character	40 (None)	(None)	(None)
2	DOMAIN	Domain Abbreviation	Character	8 (None)	(None)	(None)
3	USUBJID	Unique Subject Identifier	Character	40 (None)	(None)	(None)
4	LBSEQ	Sequence Number	Numeric	8 (None)	(None)	(None)
5	LBTESTCD	LAB Test or Examination Short Name	Character	8 (None)	(None)	(None)
6	LBTEST	LAB Test or Examination Name	Character	40 (None)	(None)	(None)
7	LBORRES	Result or Finding in Original Units	Character	25 (None)	(None)	(None)
8	LBORRESU	Original Units	Character	40 (None)	(None)	(None)
9	LBSTRESN	Numeric Result/Finding in Standard Units	Numeric	8 (None)	(None)	(None)
10	LBSTNRLO	Reference Range Lower Limit-Std Units	Numeric	8 (None)	(None)	(None)
11	LBSTNRHI	Reference Range Upper Limit-Std Units	Numeric	8 (None)	(None)	(None)
12	LBLOINC	LOINC Code	Character	200 (None)	(None)	(None)
13	LB3XNORM	3 x Normal Flag	Character	1 (None)	(None)	(None)
14	LBLEFL	Baseline Flag	Character	1 (None)	(None)	(None)
15	LBDRVFL	Derived Flag	Character	1 (None)	(None)	(None)
16	VISIT	Visit Name	Character	40 (None)	(None)	(None)
17	VISITNUM	Visit Number	Numeric	8 (None)	(None)	(None)
18	LBDTC	Date/Time of Specimen Collection	Character	64 (None)	(None)	(None)
19	LBTPNUM	Planned Time Point Number	Numeric	8 (None)	(None)	(None)

Clinical Domain Properties

Properties:

Name	Value
Classification	Special Purpose <input type="button" value="v"/>
DomainArchiveFilename	
DomainIdentifier	DM
DomainPurpose	Tabulation <input type="button" value="v"/>
DomainStructure	One record per subject <input type="button" value="v"/>
IsCustom	
IsSplit	
IsSupplemental	
UsesTemplate	true <input type="button" value="v"/>

Clinical Domain Column Properties

COUNTRY Properties

Notes | Extended Attributes | **Clinical Column**

Label:

Country

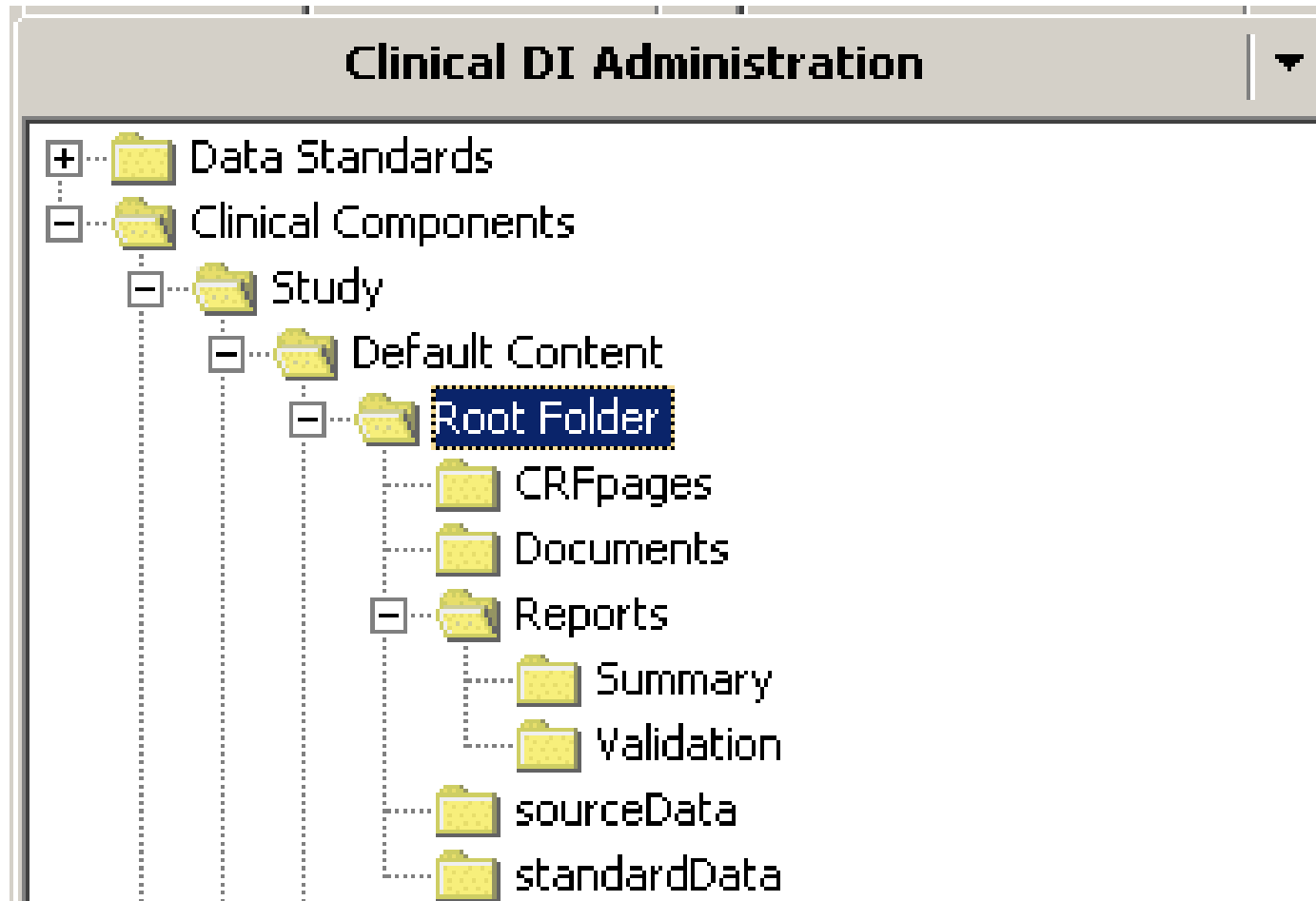
Properties:

Name	Value
Contributes to Key	false
Core	Req
Display Format	
Method	
Origin	CRF or Derived
Prefix by Identifier	false
Qualifiers	UPPERCASE
Role	ResultQualifier
Term	**ISO 3166 3-char. code
XML Codelist	COUNTRY
XML Type	text

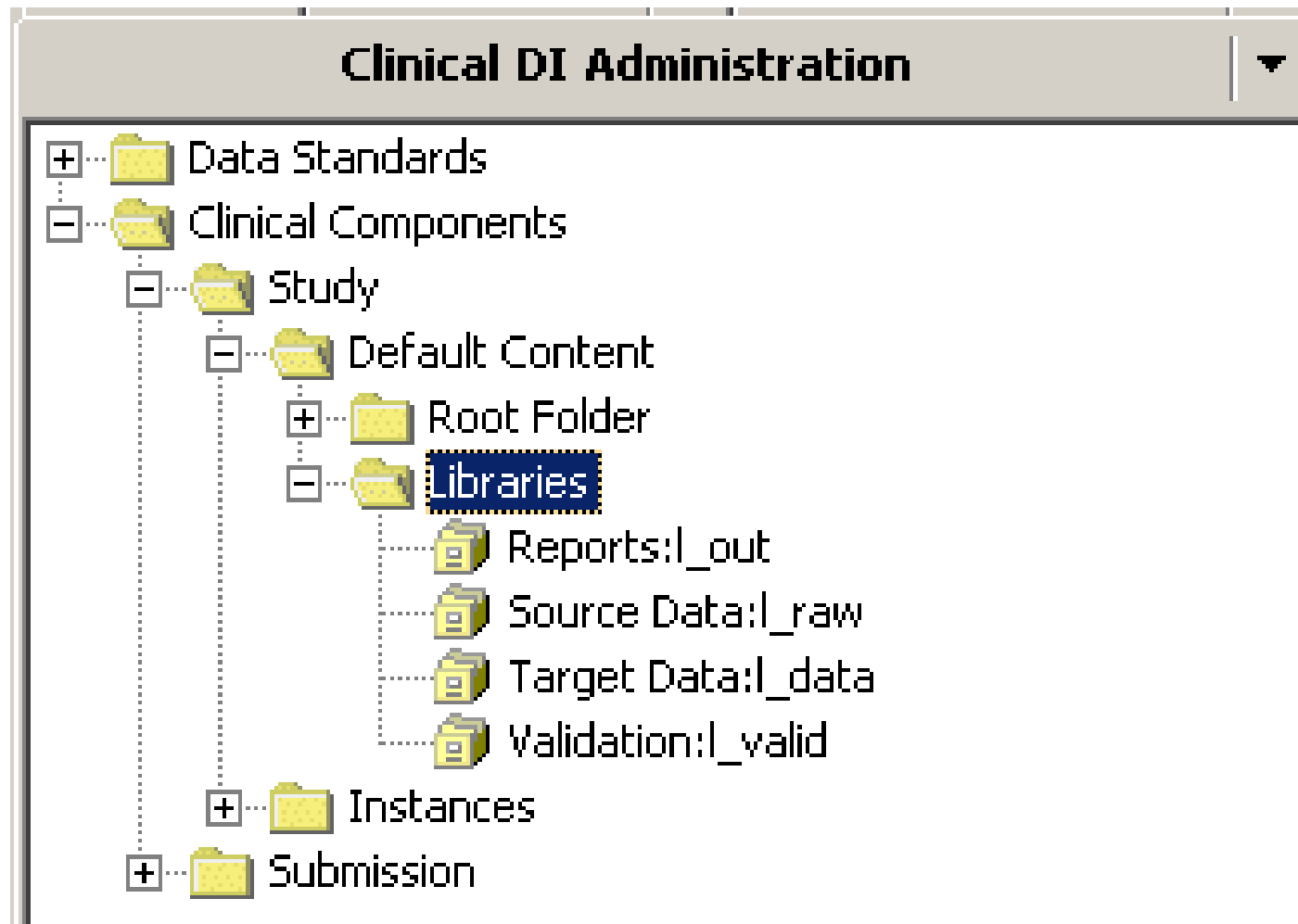
Configuration of Defaults

- Manage Clinical Components
 - Study Component
 - Study level metadata and content
 - Submission Component
 - Aggregated metadata and content
 - Collection of studies
- Define default structure for clinical components

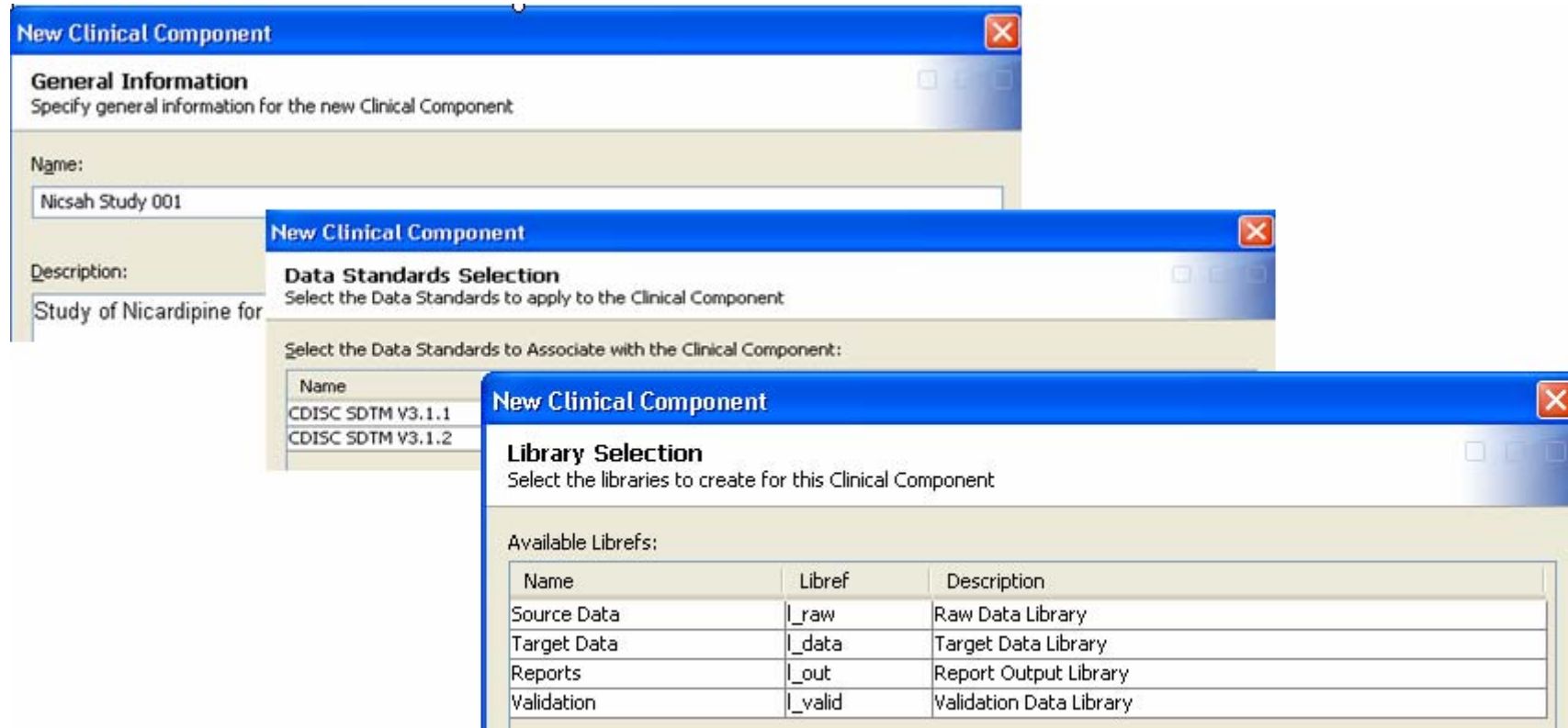
Clinical Component Defaults



Clinical Component Defaults



New Clinical Component Wizard



New Clinical Component
General Information
Specify general information for the new Clinical Component

Name:
Nicsah Study 001

Description:
Study of Nicardipine for

New Clinical Component
Data Standards Selection
Select the Data Standards to apply to the Clinical Component

Select the Data Standards to Associate with the Clinical Component:

Name
CDISC SDTM V3.1.1
CDISC SDTM V3.1.2

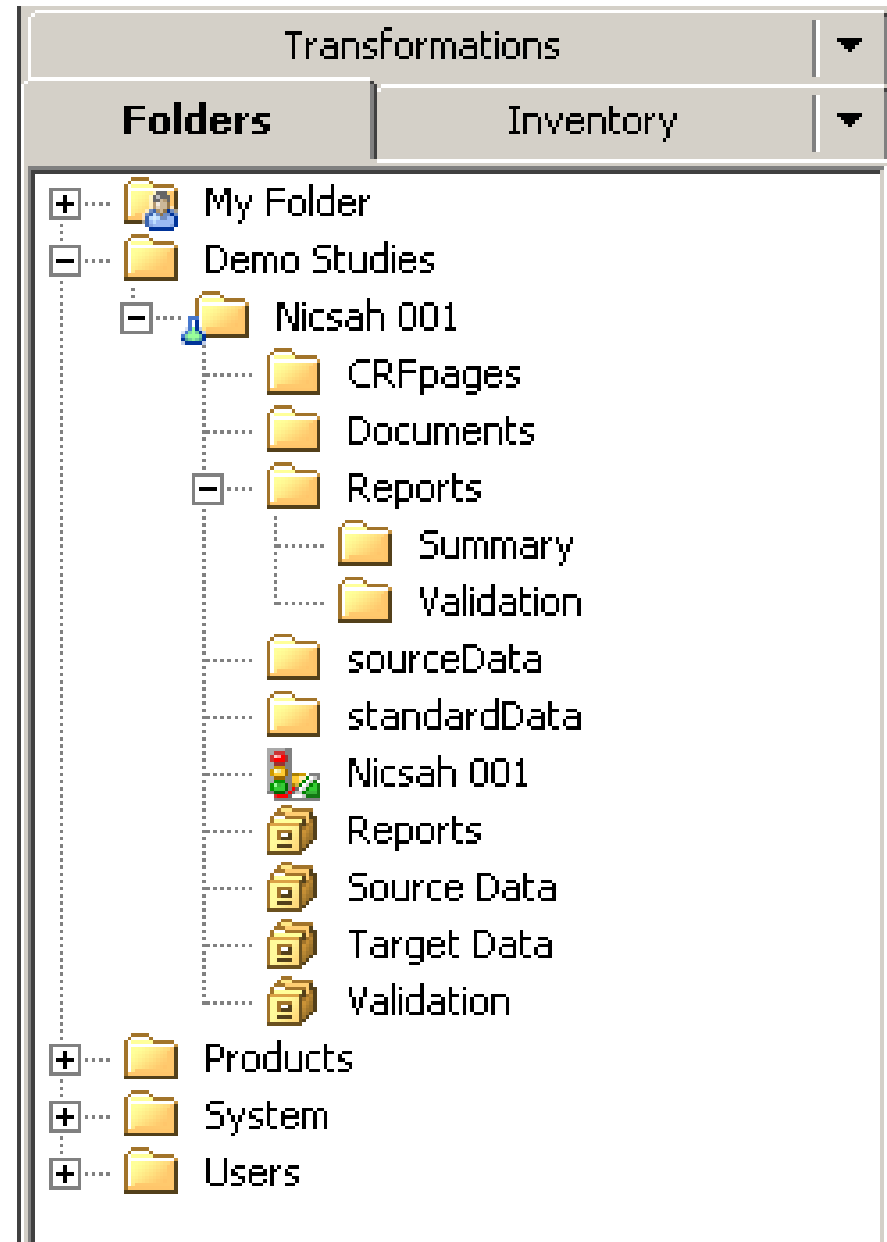
New Clinical Component
Library Selection
Select the libraries to create for this Clinical Component

Available Librefs:

Name	Libref	Description
Source Data	l_raw	Raw Data Library
Target Data	l_data	Target Data Library
Reports	l_out	Report Output Library
Validation	l_valid	Validation Data Library

Content Created

- Component Folder
- Default Folders
- Default Libraries



Creating Domains

- Data Standard Domains (templates)
- Custom Domains
- Copy Existing Domains

Create Standard Domain from Domain templates

New Standard Domain(s) ✕

Domain Template Selection □ □ □

Select the Domain Template(s) to apply

Available Domain Templates:

Identifier	Name
AE	Adverse Events
CM	Concomitant Medications
CO	Comments
DM	Demographics
DS	Disposition
DV	Protocol Deviations
EG	ECG Test Results
EX	Exposure
IE	Inclusion/Exclusion Exceptions
LB	Laboratory Tests
MH	Medical History
PE	Physical Examination
QS	Questionnaires
RELREC	Related Records
SC	Subject Characteristics

Custom Domains

- Uses the data model to construct domains
- Generalization of SDTM model to accommodate custom standards

Create Custom Domain – Select Domain Class

The screenshot shows a window titled "New Custom Domain" with a close button in the top right corner. Below the title bar, the text "Column Group Selection" is displayed, followed by the instruction "Select the column group(s) from which to get column definitions". There are three small square icons to the right of this text. The main area of the dialog is divided into two sections. The first section, labeled "Core column groups:", contains a text input field with the text "IDENTIFIERS, TIMING". The second section, labeled "Select one conditional column group (domain classifier):", contains a dropdown menu. The dropdown menu is currently open, showing a list of options: "EVENTS" (which is highlighted with a dark blue background), "FINDINGS", and "INTERVENTIONS".

Select Columns

New Custom Domain

Column Selection
Select columns for your new Domain

Available Columns:

- FINDINGS
- IDENTIFIERS
 - GRPID
 - REFID
 - SPID
- TIMING
 - VISITDY
 - TAETORD
 - DTC
 - STDTC
 - ENDTC
 - DY
 - STDY
 - ENDY
 - DUR

Selected Columns:

- FINDINGS
- TESTCD
- TEST
- MODIFY
- CAT
- SCAT
- POS
- BODSYS
- ORRES
- ORRESU
- IDENTIFIERS
- STUDYID
- DOMAIN
- USUBJID
- SEQ

Buttons: Add, Remove

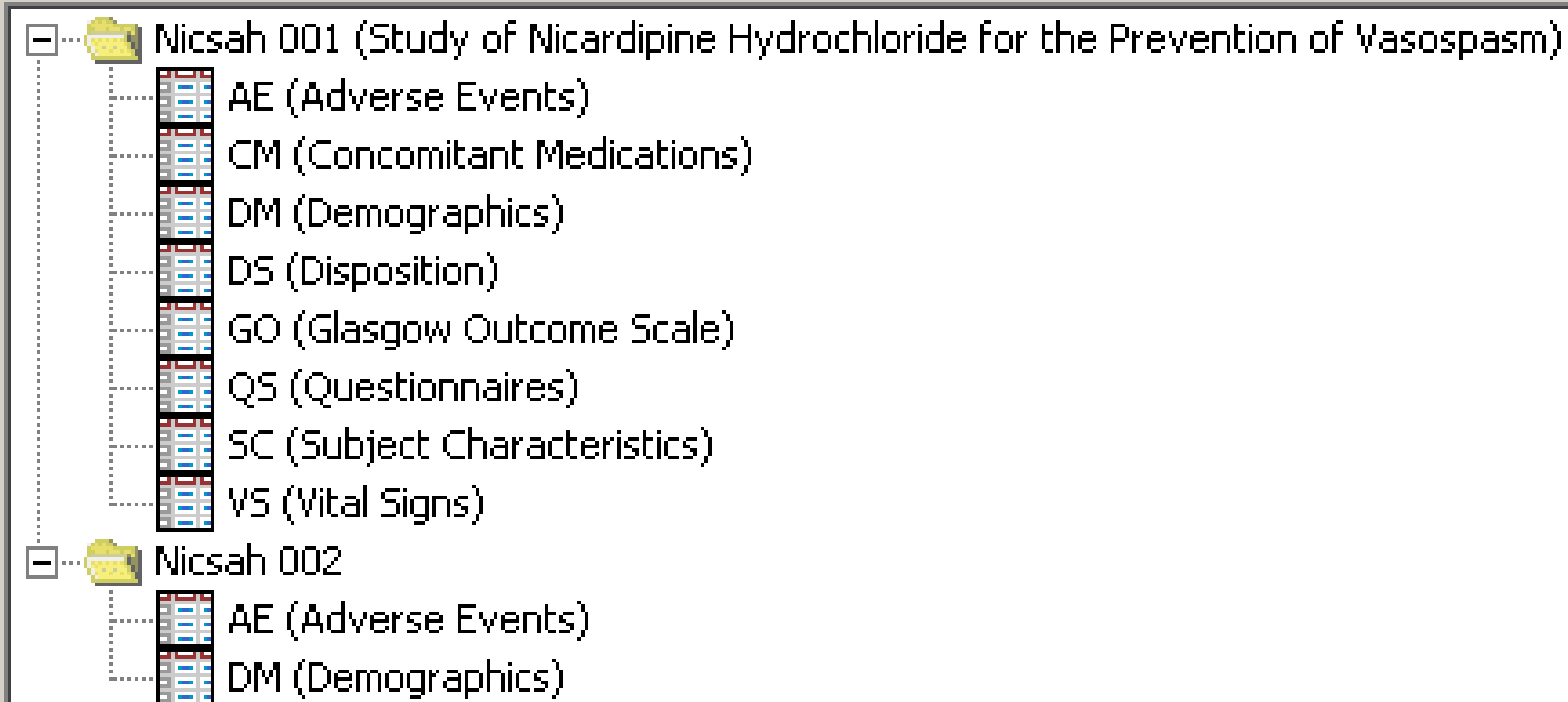
Copy Existing Domains Metadata

New Custom Domain From Existing Domain

Domain Selection

Select a custom Domain to copy

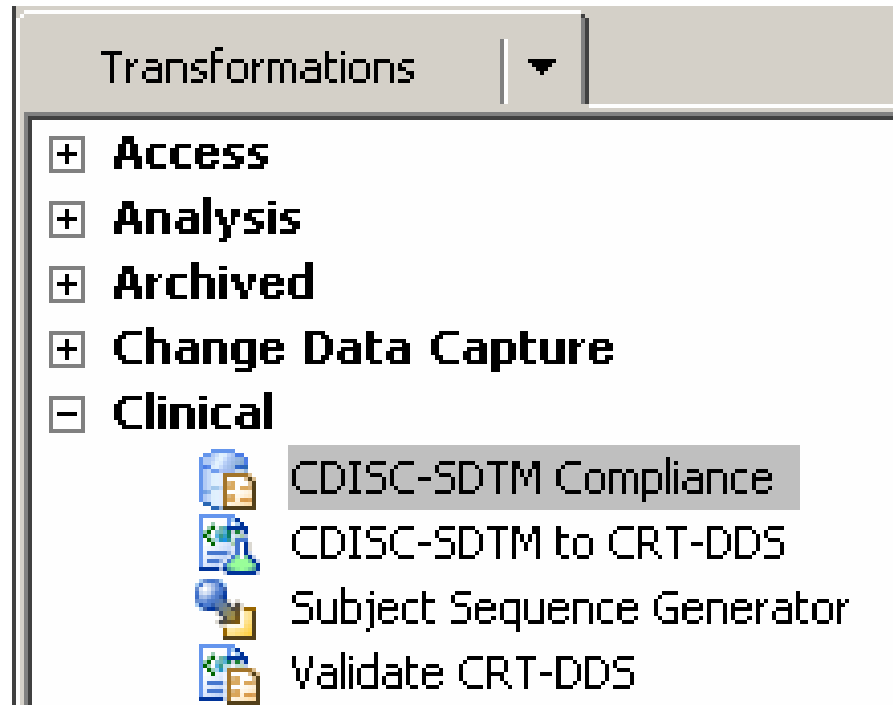
Available Domains by Clinical Component:







The screenshot displays a tree view of available domains for two studies:

- Nicsah 001 (Study of Nicardipine Hydrochloride for the Prevention of Vasospasm)**
 - AE (Adverse Events)
 - CM (Concomitant Medications)
 - DM (Demographics)
 - DS (Disposition)
 - GO (Glasgow Outcome Scale)
 - QS (Questionnaires)
 - SC (Subject Characteristics)
 - VS (Vital Signs)
- Nicsah 002**
 - AE (Adverse Events)
 - DM (Demographics)

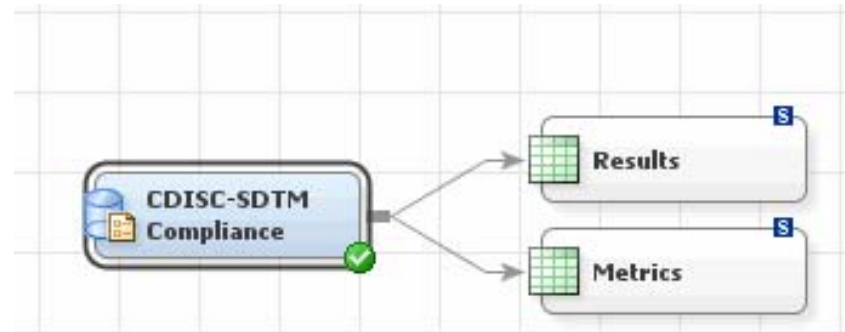
Clinical Transformations



The image shows a screenshot of the SAS Clinical Transformations menu. The menu is titled "Transformations" and is expanded to show a list of options. The options are:

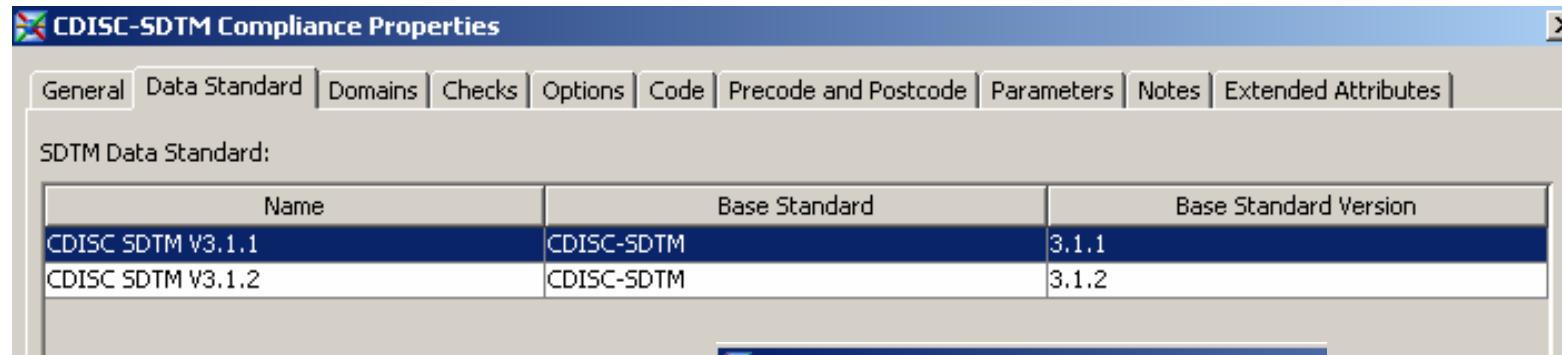
- + Access
- + Analysis
- + Archived
- + Change Data Capture
- Clinical
 -  CDISC-SDTM Compliance
 -  CDISC-SDTM to CRT-DDS
 -  Subject Sequence Generator
 -  Validate CRT-DDS

Compliance Transformation



- Validates compliance of domains against selected data standard
- Compliance checks include validation of
 - Metadata
 - Controlled terminology
 - Data Values
 - Custom
- SAS, Janus, and WebSDM™ checks included

Select Data Standard Model



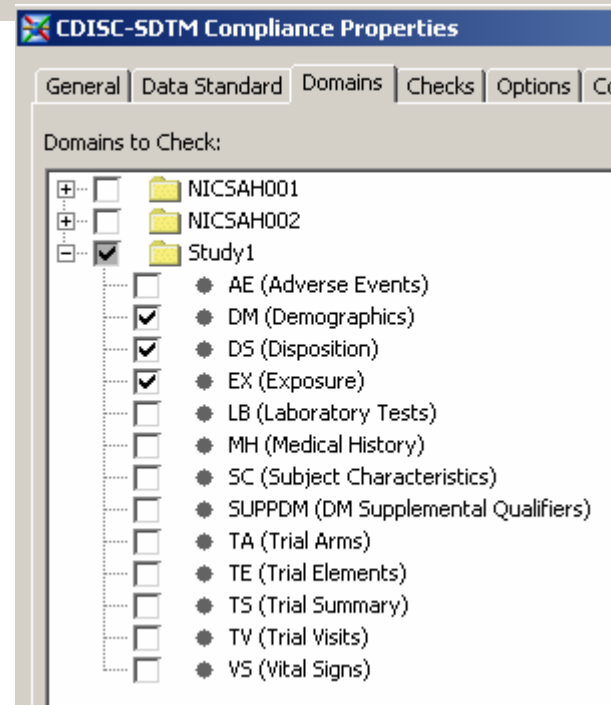
CDISC-SDTM Compliance Properties

General | Data Standard | Domains | Checks | Options | Code | Precode and Postcode | Parameters | Notes | Extended Attributes

SDTM Data Standard:

Name	Base Standard	Base Standard Version
CDISC SDTM V3.1.1	CDISC-SDTM	3.1.1
CDISC SDTM V3.1.2	CDISC-SDTM	3.1.2

- Select Domains to Validate



CDISC-SDTM Compliance Properties

General | Data Standard | Domains | Checks | Options | Code

Domains to Check:

- NICSAH001
- NICSAH002
- Study1
 - AE (Adverse Events)
 - DM (Demographics)
 - DS (Disposition)
 - EX (Exposure)
 - LB (Laboratory Tests)
 - MH (Medical History)
 - SC (Subject Characteristics)
 - SUPPDM (DM Supplemental Qualifiers)
 - TA (Trial Arms)
 - TE (Trial Elements)
 - TS (Trial Summary)
 - TV (Trial Visits)
 - VS (Vital Signs)

Select Validation Checks

Add Compliance Check(s) ✕

Checks available to be added to the selection: Show details

Check ID	Description
SDTM0001	Identifies domain table that has zero rows and therefore contains no data
SDTM0011	Identifies a column that was described in the domain description but not included in the SAS dataset for that domain
SDTM0012	Identifies a column listed in the domain description as Required ('Req') but not included in the SAS dataset for that domain
SDTM0013	Identifies a column listed in the domain description as Expected ('Exp') but not included in the SAS dataset for that domain
SDTM0015	Identifies a column that appears in the SAS dataset but is not listed in the domain description
SDTM0017	Identifies a domain that appears to contain supplemental qualifier data but does not contain the Unique Subject
SDTM0019	Identifies a variable where datatype in (study specific) description is not consistent with datatype implicit in SAS
SDTM0101	Identifies values that do not conform to the ISO 8601 standard for datetimes
SDTM0102	Identifies values that do not conform to the ISO 8601 standard for durations
SDTM0124	Identifies records that violate the condition [LENGTH(Name of Measurement, Test, or Examination (**TEST)) less than or equal to ...]
SDTM0125	Identifies records that violate the condition [LENGTH(Sort Name of Measurement, Test, or Examination (**TEST)) less than or equal to ...]
SDTM0128	Identifies records that violate the condition [LENGTH(Trial Summary Parameter (**PARM)) less than or equal to ...]
SDTM0129	Identifies records that violate the condition [LENGTH(Trial Summary Parameter Sort Name (**PARMCD)) less than or equal to ...]
SDTM0201	Identifies a null (empty) value found in a column where (Standard) Core attribute is 'Req'
SDTM0202	Identifies a null (empty) value found in a column where (Standard) Core attribute is 'Exp'
SDTM0203	Character column value is not correctly upcased per spec
SDTM0204	Character column value contains the numeric missing '.' or any special missing value like '.N'
SDTM0205	Column value is not left-justified
SDTM0206	Identifies records where the value in the Domain Abbreviation column (DOMAIN) doesn't match the name of Domain

Clinical Standards Toolkit Code Generation

Data Standard Metadata is used to generate Toolkit tables: Reference_tables, Reference_columns

```

28  /* Create reference columns data set */
29  %cst_setStandardProperties(_cstStandard=CDISC-SDTM, _cstStandardVersion=3.1
30  %cst_createds(_cstStandard=CDISC-SDTM, _cstStandardVersion=3.1
31  PROC SQL NOPRINT;
32  INSERT INTO
33  work.reference_columns
34  VALUES ("", "DM", "STUDYID", "Study Identifier", 1, "C", 40, "", "text",
35  VALUES ("", "DM", "DOMAIN", "Domain Abbreviation", 2, "C", 8, "", "te
36  VALUES ("", "DM", "USUBJID", "Unique Subject Identifier", 3, "C", 40,
37  VALUES ("", "DM", "SUBJID", "Subject Identifier for the Study", 4, "C",
38  VALUES ("", "DM", "RFSTDTG", "Subject Reference Start Date/Time", 5

```

Clinical Standards Toolkit Code Generation

Domain Metadata is used to generate Toolkit tables:
Source_tables, Source_columns

```

194 /* Create source/study tables data set */
195 %cst_setStandardProperties(_cstStandard=CDISC-SDTM, _cstStanda
196 %cst_createds(_cstStandard=CDISC-SDTM, _cstStandardVersion=3.1.
197 PROC SQL NOPRINT;
198 INSERT INTO work.source_tables
199 VALUES ("I_data", "DM", "Demographics", "Special Purpose", "..ldm.xp
200 VALUES ("I_data", "DS", "Disposition", "Events", "..lds.xpt", "", "One re
201 VALUES ("I_data", "EX", "Exposure", "Interventions", "..lex.xpt", "", "Or

```

Clinical Standards Toolkit Code Generation

Options specified on Transformation Properties page are used to generate Toolkit SASReferences dataset and macro calls

```

300 /* Create SASReferences table */
301 %cst_setStandardProperties(_cstStandard=CST-FRAMEWORK, _cstS
302 %cst_createds(_cstStandard=CST-FRAMEWORK, _cstType=control, _c
303 proc sql;
304 INSERT INTO work.sasreferences
305 VALUES ("CDISC-SDTM", "3.1.1", "sourcedata", "", "_l_data", "libref", "C
306 VALUES ("CDISC-SDTM", "3.1.1", "referencemetadata", "column", "_c
307 VALUES ("CDISC-SDTM", "3.1.1", "referencemetadata", "table", "_cdi
308 VALUES ("CDISC-SDTM", "3.1.1", "referencemetadata", "table", "_cdi
309 %cst_setStandardProperties(_cstStandard=CDISC-SDTM, _cst
310 %cst_setStandardProperties(_cstStandard=CDISC-SDTM, _cst
311 %cst_insertStandardSASRefs(_cstSASReferences=sasreferen
312 %let _cstSASRefsLoc=&_cdiwrkpath;
313 %let _cstSASRefsName=sasreferences;
314 %let _cstSASRefs=__cdiwrk.sasreferences;
315 %let _cstReallocateSasrefs=1;
316 %cstutil_allocatesasreferences;
317 %let _cstMetrics=1;
318 /* Run Compliance Code */
319 %sdtm_validate;

```

Detailed Results

Process Results, CheckID: SDTM0202

Description: Identifies a null (empty) value found in a column where (Standard) Core attribute is 'Exp'

Check scope: (Tables) _ALL_, (Columns)

Source: SAS (SAS0015)

Validation check macro: cstcheck_violatesstd, using source metadata

Source Data	Result Identifier	Message	Severity	Problem Detected?	Actual Value	Keys
SRCDATA.AE	SDTM0202	Null value in column	Note	Yes	AEREL=	STUDYID=SASCSTDEMODATA, USUBJID=S001P005,AETERM= ABDOMINAL CRAMP,AESTDTC=2008-02-22
SRCDATA.AE	SDTM0202	Null value in column	Note	Yes	AEREL=	STUDYID=SASCSTDEMODATA, USUBJID=S001P005,AETERM= PRURITIC RASH, AESTDTC=2008-03-10T21:00
SRCDATA.AE	SDTM0202	Null value in column	Note	Yes	AEREL=	STUDYID=SASCSTDEMODATA, USUBJID=S002P003,AETERM= HEADACHE, AESTDTC=2008-03-17T00:30
SRCDATA.AE	SDTM0202	Null value in column	Note	Yes	AEREL=	STUDYID=SASCSTDEMODATA, USUBJID=S002P010,AETERM= DIARRHEA, AESTDTC=2008-03-21T10:00
SRCDATA.AE	SDTM0202	Null value in column	Note	Yes	AEREL=	STUDYID=SASCSTDEMODATA, USUBJID=S002P013,AETERM= HEARTBURN, AESTDTC=2008-04-06T09:30
SRCDATA.AE	SDTM0202	Null value in column	Note	Yes	AEREL=	STUDYID=SASCSTDEMODATA, USUBJID=S002P027,AETERM= RASH, AESTDTC=2008-05-12T02:00
SRCDATA.AE	SDTM0202	Null value in column	Note	Yes	AEREL=	STUDYID=SASCSTDEMODATA, USUBJID=S002P031,AETERM= HEADACHE, AESTDTC=2008-05-21T01:30
SRCDATA.AE	SDTM0202	Null value in column	Note	Yes	AEREL=	STUDYID=SASCSTDEMODATA, USUBJID=S003P010,AETERM= PRURITIC RASH, AESTDTC=2008-06-01T14:00

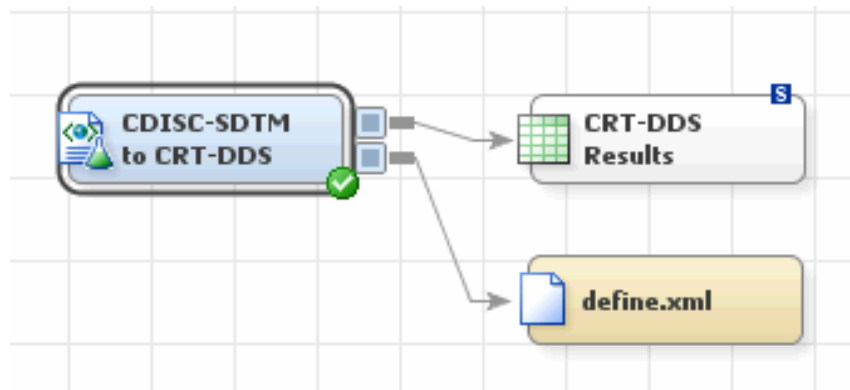
Summary Results

SAS Clinical Standards Toolkit 1.2 CDISC-SDTM 3.1.1 VALIDATION

Process Metrics

Summary Metrics		Domain Metrics				
Metric	#	Domain	# Check Invocations	# Recs (if available)	# Errors	# Check Invocations Not Run
# of distinct check invocations	14	AE	7	15	9	0
# check invocations not run	1	DM	7	30	24	0
Errors (severity=High) reported	0	DS	8	10	2	0
Warnings (severity=Medium) reported	26	EG	10	459	447	0
Notes (severity=Low) reported	1939	IE	8	9	0	0
Structural errors, warnings and notes	1	LB	10	248	236	0
Content errors, warnings and notes	1965	SC	9	14	4	0
		SU	9	50	40	0
		SUPPAE	6	6	1	0
		SV	6	6	0	0
		TA	5	13	9	0
		TE	5	5	0	0
		TI	5	5	0	0
		TS	5	5	0	0
		TV	5	9	5	0
		VS	10	1200	1188	0

Publish Define.xml file



- Select Domains to include
- Select define.xml generation options
 - Customize style sheet
 - Output Encoding

Clinical Standards Toolkit Code is Generated

```

92  /* Create cstsasreferences table */
93
94  %let _cstSASRefs=work.sasreferences;
95  %let _cstSASRefsLoc=&workpath;
96  %let _cstSASRefsName=sasreferences;
97  %cst_setStandardProperties(_cstStandard=CST-FRAMEWORK, _cstSubType=i
98  %cst_createds(_cstStandard=CST-FRAMEWORK, _cstType=control, _cstSubTyp
99  proc sql;
100  INSERT INTO work.sasreferences
101  136  /* Create Study Staging CRT-DDS Datasets */
102  137  %cst_setStandardProperties(_cstStandard=CDISC-SDTM, _cstStandardVersior
103  138  %cst_createds(_cstStandard=CDISC-SDTM, _cstStandardVersion=3.1.1, _cstTy
104  139  PROC SQL NOPRINT;
140  INSERT INTO work.source_tables
141  VALUES ("1", "AE", "Adverse Events", "Events", "..lae.xpt", "", "One record per
142  433  %let _cstSASRefs=work.sasreferences;
143  434  %let _cstSASRefsLoc=&workpath;
144  435  %let _cstSASRefsName=sasreferences;
145  436  /* Transform CDISC-SDTM domains to CRT-DDS file; */
146  437  %crtdds_sdtm311todefined10(_cstOutLib=work, _cstSourceTables=work.source_tables, _
147  438  %crtdds_write(_cstCreateDisplayStyleSheet=1, _cstResultsOverrideDS=crtdds_results,
148  439  _cstOutputEncoding=UTF-8, _cstHeaderComment=Produced from SAS data using the SA
149  440
150  441

```


Define.xml

Study ABC, Data Definitions - Microsoft Internet Explorer provided by SAS

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites Home Mail Print Stop Taskbar Links

Address C:\temp\Pharmasug\define\define_w2.xml Go Links >>

Datasets for Study ABC					
Dataset	Description	Structure	Purpose	Keys	Location
AE	Adverse Events	Events - One record per adverse event per subject	Tabulation	STUDYID, USUBJID, AETERM, AESTDTC	ae.xpt
CM	Concomitant Medications	Interventions - One record per medication intervention episode per subject	Tabulation	STUDYID, USUBJID, CMTRT, CMSTDTC	cm.xpt
DM	Demographics	Special Purpose - One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt
DS	Disposition	Events - One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSSTDTC	ds.xpt
EX	Exposure	Interventions - One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXTRT, EXSTDTC	ex.xpt
LB	Laboratory Tests	Findings - One record per lab test	Tabulation	STUDYID, USUBJID, TESTCD, TESTCDL, TESTRES, TESTRESL	lb.xpt

Monitor Domain Status

Domain Status: Nicsah Study 01

Domains:

#	Name	ID	Description	Is Mapped?	Is Validated?	Locked By
1	DS	DS	Disposition	Yes	No	Julie.Maddox
2	AE	AE	Adverse Events	Yes	No	
3	GO	GO	Glasgow Outcome Scale	No	No	
4	DM	DM	Demographics	Yes	Yes	
5	CM	CM	Concomitant Medications	Yes	No	
6	QS	QS	Questionnaires	No	No	
7	SC	SC	Subject Characteristics	Yes	No	

Print...

Close

Analyze Use of Data Standard

Analyze Model Usage: CDISC SDTM V3.1.1

Clinical Components:

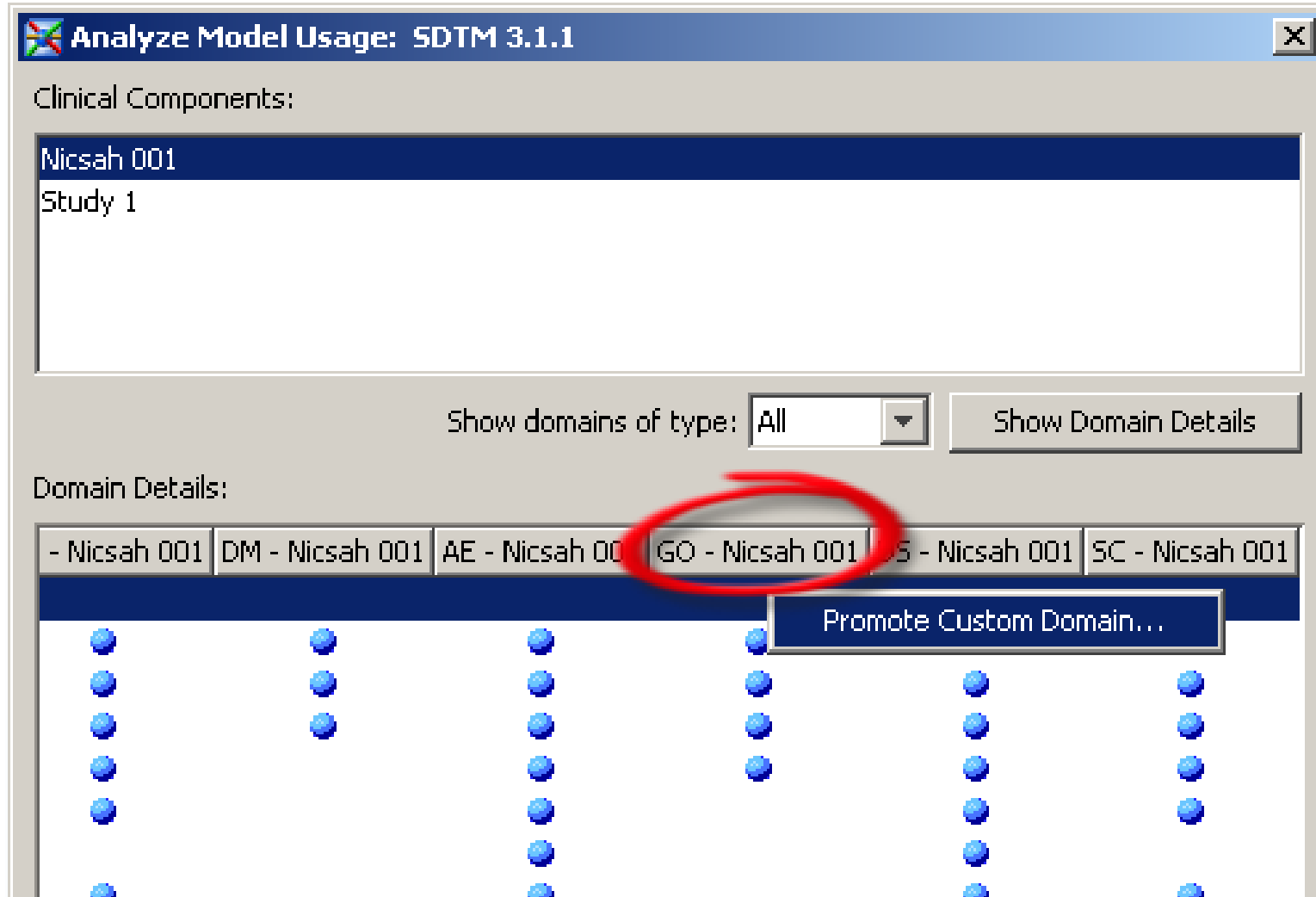
- StudyA1
- StudyA2

Show domains of type:

Domain Details:

Columns	AE	AE	DM (2)	DS	DS	EX	EX	LB	LB	MH (2)	SC (2)	SUPP
IDENTIFIERS												
FINDINGS												
EVENTS												
● TERM	■	■		■	■					■		
● MODIFY	■											
● DECOD	■	■		■	■					■		
● CAT	■			■	■	■		■	■	■		■
● SCAT	■				■	■			■			■
● OCCUR	■									■		
● STAT									■			■
● REASND									■			■
● BODSYS	■	■								■		
● LOC	■					■						
● SEV	■	■										
● SER	■	■										
● ACN	■	■										

Promote Custom Domains



Analyze Model Usage: SDTM 3.1.1

Clinical Components:

Nicsah 001
Study 1

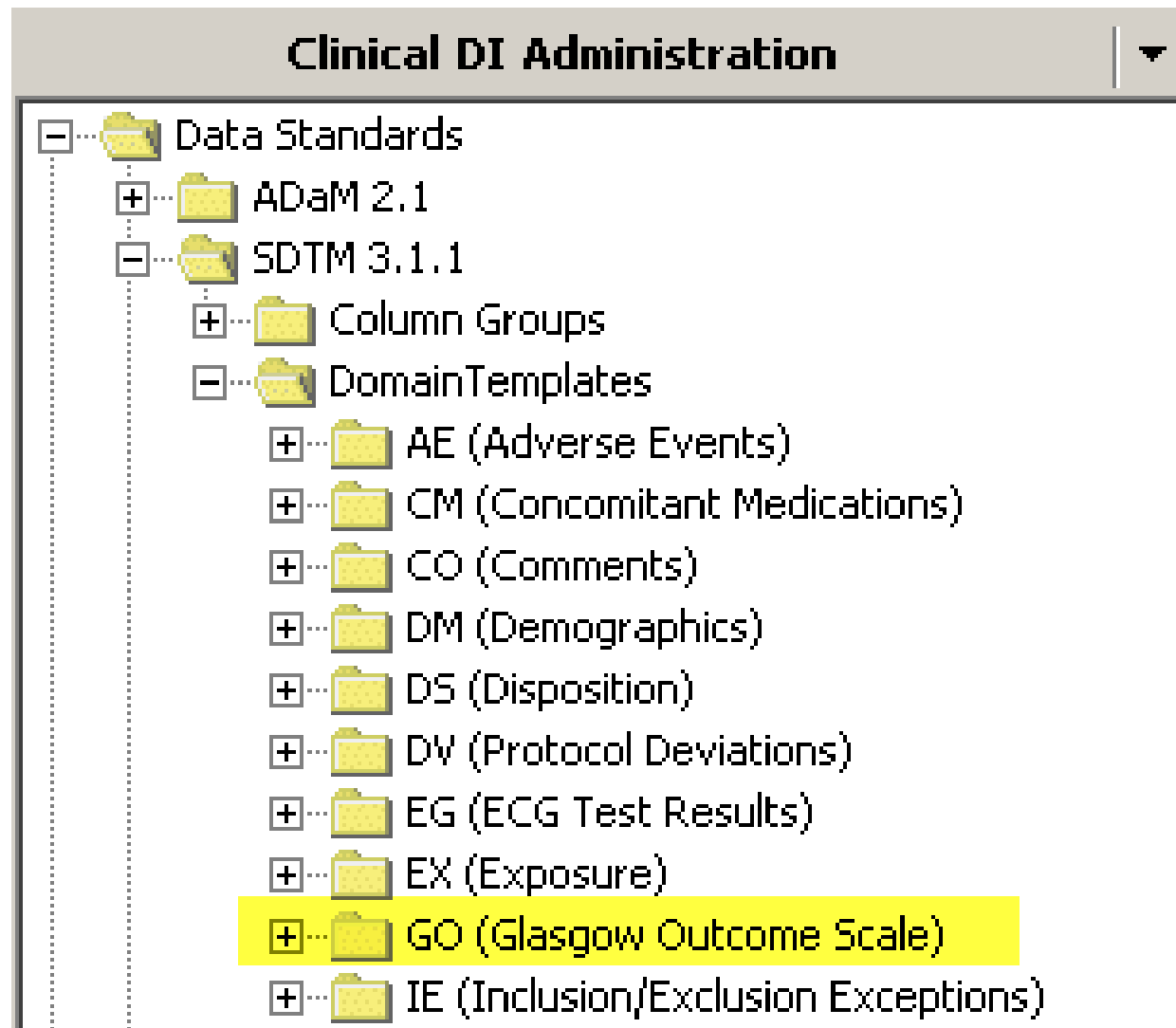
Show domains of type: All Show Domain Details

Domain Details:

- Nicsah 001	DM - Nicsah 001	AE - Nicsah 001	GO - Nicsah 001	OS - Nicsah 001	SC - Nicsah 001
●	●	●	●	●	●
●	●	●	●	●	●
●	●	●	●	●	●
●	●	●	●	●	●
●	●	●	●	●	●
●	●	●	●	●	●
●	●	●	●	●	●

Promote Custom Domain...

Promote Custom Domains into Data Standard



Summary

SAS Clinical Data Integration

- Standardization - Expedite data standardization through reuse of metadata
- Consistency - Automate setup of studies, controlled terminology, and transformation processes
- Conformance – Validate against data standard, customize conformance checks
- Administration - Monitor the consistency, and use of standards within an organization

Questions ?



Thank you, and enjoy the conference



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