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

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

SDTM Classes

SDTM Domains
Customizing Data Standards

- SDTM Standard LB Domain
Customizing Data Standards

- Customized LB Domain (SDTM +/-)

<table>
<thead>
<tr>
<th>#</th>
<th>Name</th>
<th>Description</th>
<th>Type</th>
<th>Length</th>
<th>Informac</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>STUDYID</td>
<td>Study Identifier</td>
<td>Character</td>
<td>40</td>
<td>(None)</td>
<td>None</td>
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<tr>
<td>2</td>
<td>DOMAIN</td>
<td>Domain Abbreviation</td>
<td>Character</td>
<td>6</td>
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<tr>
<td>3</td>
<td>USUBJID</td>
<td>Unique Subject Identifier</td>
<td>Character</td>
<td>40</td>
<td>(None)</td>
<td>None</td>
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<tr>
<td>4</td>
<td>LBSEQ</td>
<td>Sequence Number</td>
<td>Numeric</td>
<td>8</td>
<td>(None)</td>
<td>None</td>
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<tr>
<td>5</td>
<td>LBTTESTCD</td>
<td>LAB Test or Examination Short Name</td>
<td>Character</td>
<td>8</td>
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<td>None</td>
</tr>
<tr>
<td>6</td>
<td>LBTTEST</td>
<td>LAB Test or Examination Name</td>
<td>Character</td>
<td>40</td>
<td>(None)</td>
<td>None</td>
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<tr>
<td>7</td>
<td>LBORRES</td>
<td>Result or Finding in Original Units</td>
<td>Character</td>
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<td>None</td>
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<td>8</td>
<td>LBORRESJ</td>
<td>Original Units</td>
<td>Character</td>
<td>40</td>
<td>(None)</td>
<td>None</td>
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<td>Numeric Result/Finding in Standard Units</td>
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<td>10</td>
<td>LBSRNLLO</td>
<td>Reference Range Lower Limit-Std Units</td>
<td>Numeric</td>
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<td>None</td>
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<tr>
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<td>LBSRNHILE</td>
<td>Reference Range Upper Limit-Std Units</td>
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<td>LOINC Code</td>
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<tr>
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<td>S x Normal Flag</td>
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<td>None</td>
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<tr>
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<td>Baseline Flag</td>
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<td>Derived Flag</td>
<td>Character</td>
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<td>VISIT</td>
<td>Visit Name</td>
<td>Character</td>
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<td>VISITNUM</td>
<td>Visit Number</td>
<td>Numeric</td>
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<td>None</td>
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<td>18</td>
<td>LBTOTC</td>
<td>Date/Time of Specimen Collection</td>
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Clinical Domain Properties

<table>
<thead>
<tr>
<th>Name</th>
<th>Value</th>
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<tbody>
<tr>
<td>Classification</td>
<td>Special Purpose</td>
</tr>
<tr>
<td>DomainArchiveFilename</td>
<td></td>
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<tr>
<td>DomainIdentifier</td>
<td>DM</td>
</tr>
<tr>
<td>DomainPurpose</td>
<td>Tabulation</td>
</tr>
<tr>
<td>DomainStructure</td>
<td>One record per subject</td>
</tr>
<tr>
<td>IsCustom</td>
<td></td>
</tr>
<tr>
<td>IsSplit</td>
<td></td>
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<tr>
<td>IsSupplemental</td>
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<tr>
<td>UsesTemplate</td>
<td>true</td>
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Clinical Domain Column Properties

![Image of Clinical Domain Column Properties](image-url)

<table>
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<tr>
<th>Properties</th>
<th>Value</th>
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<tr>
<td>Contributes to Key</td>
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<tr>
<td>Core</td>
<td>Req</td>
</tr>
<tr>
<td>Display Format</td>
<td></td>
</tr>
<tr>
<td>Method</td>
<td></td>
</tr>
<tr>
<td>Origin</td>
<td>CRF or Derived</td>
</tr>
<tr>
<td>Prefix by Identifier</td>
<td>false</td>
</tr>
<tr>
<td>Qualifiers</td>
<td>UPPERCASE</td>
</tr>
<tr>
<td>Role</td>
<td>ResultQualifier</td>
</tr>
<tr>
<td>Term</td>
<td>**ISO 3166 3-char. code</td>
</tr>
<tr>
<td>XML Codelist</td>
<td>COUNTRY</td>
</tr>
<tr>
<td>XML Type</td>
<td>text</td>
</tr>
</tbody>
</table>
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 DI Administration

- Data Standards
- Clinical Components
  - Study
    - Default Content
      - Root Folder
        - CRFpages
        - Documents
        - Reports
          - Summary
          - Validation
          - sourceData
          - standardData
Clinical Component Defaults
New Clinical Component Wizard

General Information
Specify general information for the new Clinical Component:

Name: Ncsah Study 001
Description: Study of Nicardipine for

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

Name
CDISC SDTM V3.1.1
CDISC SDTM V3.1.2

Select the Data Standards to Associate with the Clinical Component:

Library Selection
Select the libraries to create for the Clinical Component:

Available Librefs:

<table>
<thead>
<tr>
<th>Name</th>
<th>Libref</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source Data</td>
<td>raw</td>
<td>Raw Data Library</td>
</tr>
<tr>
<td>Target Data</td>
<td>data</td>
<td>Target Data Library</td>
</tr>
<tr>
<td>Reports</td>
<td>out</td>
<td>Report Output Library</td>
</tr>
<tr>
<td>Validation</td>
<td>valid</td>
<td>Validation Data Library</td>
</tr>
</tbody>
</table>
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
Custom Domains

- Uses the data model to construct domains
- Generalization of SDTM model to accommodate custom standards
Create Custom Domain – Select Domain Class

**Column Group Selection**
Select the column group(s) from which to get column definitions

Core column groups:
- IDENTIFIERS, TIMING

Select one conditional column group (domain classifier):
- EVENTS
- EVENTS
- FINDINGS
- 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
Copy Existing Domains Metadata

Available Domains by Clinical Component:

- 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

- 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

- Select Domains to Validate
Select Validation Checks

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

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

```sql
/* Create reference columns data set */
%cst_setStandardProperties(_cstStandard=CDISC-SDTM, _cstStandardVersion=3.1)
%cst_created(_cstStandard=CDISC-SDTM, _cstStandardVersion=3.1)
PROC SQL NOPRINT;
INSERT INTO
  work.reference_columns
VALUES ("", "DM", "STUDYID", "Study Identifier", 1, "C", 40, ",", "text",
VALUES ("", "DM", "DOMAIN", "Domain Abbreviation", 2, "C", 8, ",", "te",
VALUES ("", "DM", "USUBJID", "Unique Subject Identifier", 3, "C", 40,
VALUES ("", "DM", "SUBJID", "Subject Identifier for the Study", 4, "C",
VALUES ("", "DM", "RFSTDTC", "Subject Reference Start Date/Time", 5
```
Clinical Standards Toolkit Code Generation

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

/* Create source/study tables data set */
%cst_setStandardProperties(_cstStandard=CDISC-SDTM, _cstStanda
PROC SQL NOPRINT;
INSERT INTO work.source_tables
VALUES ("l_data", "DM", "Demographics", "Special Purpose", "..\dm.xp
VALUES ("l_data", "DS", "Disposition", "Events", "..\ds.xpt", ", "One re
VALUES ("l_data", "EX", "Exposure", "Interventions", "..\ex.xpt", ", "Or
Clinical Standards Toolkit Code Generation

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

```sql
PROC SQL;
INSERT INTO work.sasreferences
VALUES ('CDISC-SDTM', '3.1.1', '', 'l_data', 'libref', 'c','CDISC-SDTM', '3.1.1', 'reference metadata', 'column', '
'__cdiv
VALUES ('CDISC-SDTM', '3.1.1', 'reference metadata', 'table', '__cdiv
308 %cst_setStandardProperties(_catStandard=CDISC-SDTM, _cst
309 %cst_setStandardProperties(_catStandard=CDISC-SDTM, _cst
310 %cst_insertStandardSASRefs(_cstSASReferences=sasreferences
311 %let_cstSASRefsLoc=&_cdiwpth;
312 %let_cstSASRefsName=sasreferences;
313 %let_cstSASRefs=_cdiwrk.sasreferences;
314 %let_cstAllocateSasrefs=1;
315 %cstutil_alllocatesasreferences;
316 %let_cstMetrics=1;
317 /* Run Compliance Code */
318 %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: csccheck_violatesstd, using source metadata

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

**SAS Clinical Standards Toolkit 1.2**  
**CDISC-SDTM 3.1.1 VALIDATION**

#### Process Metrics

<table>
<thead>
<tr>
<th>Metric</th>
<th>#</th>
<th>Domain</th>
<th># Check Invocations</th>
<th># Recs (if available)</th>
<th># Errors</th>
<th># Check Invocations Not Run</th>
</tr>
</thead>
<tbody>
<tr>
<td># of distinct check invocations</td>
<td>14</td>
<td>AE</td>
<td>7</td>
<td>15</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td># check invocations not run</td>
<td>1</td>
<td>DM</td>
<td>7</td>
<td>30</td>
<td>24</td>
<td>0</td>
</tr>
<tr>
<td>Errors (severity=High) reported</td>
<td>0</td>
<td>DS</td>
<td>8</td>
<td>10</td>
<td>2</td>
<td>0</td>
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<tr>
<td>Warnings (severity=Medium) reported</td>
<td>26</td>
<td>EG</td>
<td>10</td>
<td>459</td>
<td>447</td>
<td>0</td>
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<tr>
<td>Notes (severity=Low) reported</td>
<td>1939</td>
<td>IE</td>
<td>8</td>
<td>9</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Structural errors, warnings and notes</td>
<td>1</td>
<td>LB</td>
<td>10</td>
<td>248</td>
<td>236</td>
<td>0</td>
</tr>
<tr>
<td>Content errors, warnings and notes</td>
<td>1965</td>
<td>SC</td>
<td>9</td>
<td>14</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SU</td>
<td>9</td>
<td>50</td>
<td>40</td>
<td>0</td>
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<tr>
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<td>SUPPAE</td>
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<td>6</td>
<td>1</td>
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<td>1200</td>
<td>1188</td>
<td>0</td>
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</tbody>
</table>
Publish Define.xml file

- Select Domains to include
- Select define.xml generation options
  - Customize style sheet
  - Output Encoding
%let_cstSASRefs=work.sasreferences;
%let_cstSASRefsLoc=&workpath;
%let_cstSASRefsName=sasreferences;
%setStandardProperties(_cstStandard=CST-FRAMEWORK, _cstSubType=individual, _cst_version=3.1.1, _cst_type=control, _cstSubType=individual, _cstVersion=3.1.1, _cstRead=file, _cstWrite=file, _cstOutputEncoding=UTF-8, _cstHeaderComment=Produced from SAS data using the SA

proc sql;
insert into work.sasreferences
values (1, "AE", "Adverse Events", "Events", ".\ae.xpt", ",", "One record per domain");
%let_cstSASRefs=work.sasreferences;
%let_cstSASRefsLoc=&workpath;
%let_cstSASRefsName=sasreferences;
%setStandardProperties(_cstStandard=CDISC-SDTM, _cstStandardVersion=3.1.1, _cstSubType=individual, _cstVersion=3.1.1, _cstRead=file, _cstWrite=file, _cstOutputEncoding=UTF-8, _cstHeaderComment=Produced from SAS data using the SA

/* Transform CDISC-SDTM domains to CRT-DDS file */
crd_tdm311_todefines(_cstOutLib=work, _cstSourceTables=work.source_tables, _
crd_tdm311_write(_cstCreateDisplayStyleSheet=1, _cstResultsOverrideDS=crtdds_results, _
cstOutputEncoding=UTF-8, _cstHeaderComment=Produced from SAS data using the SA

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# Define.xml

## Datasets for Study ABC

<table>
<thead>
<tr>
<th>Dataset</th>
<th>Description</th>
<th>Structure</th>
<th>Purpose</th>
<th>Keys</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>AE</td>
<td>Adverse Events</td>
<td>Events - One record per adverse event per subject</td>
<td>Tabulation</td>
<td>STUDYID, USUBJID, AETERM, AESTDTC</td>
<td>ae.xpt</td>
</tr>
<tr>
<td>CM</td>
<td>Concomitant Medications</td>
<td>Interventions - One record per medication intervention episode per subject</td>
<td>Tabulation</td>
<td>STUDYID, USUBJID, CMTRT, CMSTDTC</td>
<td>cm.xpt</td>
</tr>
<tr>
<td>DM</td>
<td>Demographics</td>
<td>Special Purpose - One record per subject</td>
<td>Tabulation</td>
<td>STUDYID, USUBJID</td>
<td>dm.xpt</td>
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<tr>
<td>DS</td>
<td>Disposition</td>
<td>Events - One record per disposition status or protocol milestone per subject</td>
<td>Tabulation</td>
<td>STUDYID, USUBJID, DSSTDTC</td>
<td>ds.xpt</td>
</tr>
<tr>
<td>EX</td>
<td>Exposure</td>
<td>Interventions - One record per constant dosing interval per subject</td>
<td>Tabulation</td>
<td>STUDYID, USUBJID, EXTRT, EXSTDTC</td>
<td>ex.xpt</td>
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<tr>
<td>LB</td>
<td>Laboratory Tests</td>
<td>Findings - One record per lab test</td>
<td>Tabulation</td>
<td>STUDYID, USUBJID, LTESTID, LTESTIDT</td>
<td>lb.xpt</td>
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</tbody>
</table>
Monitor Domain Status

![Domain Status: Nicsah Study 01](image)

### Domains:

<table>
<thead>
<tr>
<th>#</th>
<th>Name</th>
<th>ID</th>
<th>Description</th>
<th>Is Mapped?</th>
<th>Is Validated?</th>
<th>Locked By</th>
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<td>No</td>
<td>Julie.Maddox</td>
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<td>2</td>
<td>AE</td>
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<td>Adverse Events</td>
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<td>No</td>
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<tr>
<td>3</td>
<td>GO</td>
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<td>Glasgow Outcome Scale</td>
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<td>No</td>
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<td>Demographics</td>
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<tr>
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<td>CM</td>
<td>CM</td>
<td>Concomitant Medications</td>
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<td>No</td>
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<td>Questionnaires</td>
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<td>No</td>
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<td>7</td>
<td>SC</td>
<td>SC</td>
<td>Subject Characteristics</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

[Print... button]

[Close button]
Analyze Use of Data Standard
Promote Custom Domains
Promote Custom Domains into Data Standard

Clinical DI Administration

- Data Standards
  - ADaM 2.1
  - SDTM 3.1.1
    - Column Groups
    - DomainTemplates
      - AE (Adverse Events)
      - CM (Concomitant Medications)
      - CO (Comments)
      - DM (Demographics)
      - DS (Disposition)
      - DV (Protocol Deviations)
      - EG (ECG Test Results)
      - EX (Exposure)
      - GO (Glasgow Outcome Scale)
      - IE (Inclusion/Exclusion Exceptions)
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