USING THE SAS® CLINICAL STANDARDS TOOLKIT 1.5 TO IMPORT CDISC ODM FILES

LEX JANSEN, SAS, CDISC XML TECHNOLOGIES TEAM
AGENDA

- Introduction to the SAS® Clinical Standards Toolkit (CST)
- Operational Data Model (ODM)
- SAS Data Model for ODM
- SAS Clinical Standards Toolkit
  - Framework
  - Metadata files
- SAS Clinical Standards Toolkit - Hands-On
• **Framework** to primarily support **Clinical Research** activities.
  
  Initially focusing on standards as defined by CDISC, but not limited to CDISC.
  
  Designed as an integral part of **Clinical Data Integration** (CDI), but is 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**
• 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)
• Supported CDISC standards in Toolkit 1.5:
  • **SDTM** 3.1.1, 3.1.2 and 3.1.3
  • **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)
  • **ODM** 1.3.0, 1.3.1 - Read / Write / Validate
  • **NCI CDISC Controlled Terminology** (December 2012) (import/export of ODM XML through CT 1.0 standard)
• Supported with SAS 9.3M2 on the following operating systems:
  • Windows 32
  • Windows for x64
  • Linux for x64
  • Solaris x64 SPARC
• Separately orderable component
• Available at no additional charge to currently licensed SAS customers.
• Contact your SAS Account Representative concerning availability
• XML standard published by CDISC
• Support data interchange and archive
• Represent an entire clinical study
  • Study metadata
  • Administrative metadata
  • Reference data
  • Subject data
  • Audit information
• Comply with 21 CFR Part 11 (and associated regulatory requirements)
• Designed to be compatible with clinical data applications
• Platform and Vendor neutral
ODM Version 1.3.1

ODM version 1.3.1 is available here

You can download the standard as separate elements:

- ODM 1.3.1.xsd
- ODM 1.3.1 Final.html
- ODM 1.3.1 Foundation.xsd
- Read Me.txt
- xlink.xsd
- xml.xsd
- xmlsig core schema.xsd
CDISC

Clinical Data Interchange Standards Consortium

Specification for the Operational Data Model (ODM)

Version 1.3.1 Production
Source File: ODM1-3-1.htm
Last Update: 2010-02-11

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An official copy of this document is available on the ODM page of the CDISC website http://www.cdisc.org/odm.
ODM Version 1.3.1

You can download the standard as separate elements:

- ODM 1.3.1.xsd
- ODM 1.3.1 Final.html
- ODM 1.3.1 Foundation.xsd
- Read Me.txt
- xlink.xsd
- xml.xsd
- xmldsig core schema.xsd
OPERATIONAL DATA MODEL (ODM)

- **Extensible** by design
- Foundation for other CDISC production standards:
  - Define-XML (CRT-DDS, define.xml)
  - SDM-XML (Study Design Model)
  - ODM-CT-XML (Controlled Terminology in ODM)

- (to follow: CDASH-ODM, xxx-ODM)
OPERATIONAL DATA MODEL (ODM)

- Foundation for Define-XML 1.0
• Foundation for Define-XML 2.0
• Foundation for ODM XML Controlled Terminology
• ODM in XML has a deep hierarchy and many relations
• ODM in XML has a deep hierarchy and many relations
<Protocol>
  <Description>
    <TranslatedText xml:lang="en">Protocol description</TranslatedText>
    <TranslatedText xml:lang="fr-CA">Description du protocole</TranslatedText>
  </Description>
  <StudyEventRef Mandatory="Yes" OrderNumber="1" StudyEventOID="StudyEventDefs.OID1.Screening"/>
</Protocol>

<StudyEventDef OID="StudyEventDefs.OID1.Screening" Category="Screening"
    Name="Screening" Repeating="No" Type="Scheduled">
  <FormRef FormOID="FormDefs.MH" Mandatory="Yes" OrderNumber="1"/>
</StudyEventDef>

<FormDef OID="FormDefs.MH" Name="Medical History" Repeating="No">
  <ItemGroupRef ItemGroupOID="ItemGroupDefs.mh.idss" Mandatory="Yes" OrderNumber="0"/>
  <ItemGroupRef ItemGroupOID="ItemGroupDefs.mh.events" Mandatory="Yes" OrderNumber="1"/>
</FormDef>

<ItemGroupDef OID="ItemGroupDefs.OID.mh.events" Name="Medical History Event Columns" Repeating="Yes"
    IsReferenceData="No" SASDataSetName="mh_evt" Domain="MH" Purpose="Tabulation">
  <ItemRef ItemOID="ItemDef.OID.MH.MHSTAT" Mandatory="No" OrderNumber="15" Role="RecordQualifier"/>
  <ItemRef ItemOID="ItemDef.OID.MH.MHREASND" Mandatory="No" OrderNumber="16" Role="RecordQualifier"/>
</ItemGroupDef>

<ItemDef OID="ItemDef.OID.MH.MHSTAT" Name="MHSTAT" DataType="string" Length="40" SASFieldName="MHSTAT"
    Comment="The status indicates that the pre-specified question was not answered.">
  <CodeListRef CodeListOID="CodeLists.OID.ND"/>
</ItemDef>

<CodeList OID="CodeLists.OID.ND" Name="ND" DataType="text" SASFormatName="&ND">
  <CodeListItem CodedValue="ND">
    <Decode>
      <TranslatedText xml:lang="en">NOT DONE</TranslatedText>
      <TranslatedText xml:lang="sw">SI KUFANYIKA</TranslatedText>
      <TranslatedText xml:lang="si">සිංහාභාෂය</TranslatedText>
    </Decode>
  </CodeListItem>
</CodeList>
• SAS Clinical Standards Toolkit v1.5 provides data model that represents the ODM Version 1.3.1 format in 76 SAS data sets
• Patterned to match the XML element and attribute structure of the ODM XML format
• XML element → table, XML attribute → column
<ItemGroupDef OID="ItemGroupDefs.OID.DM" Name="DM" Repeating="No">
  IsReferenceData="No" SASDatasetName="DM" Domain="DM" Purpose="Tabulation">
    <ItemRef ItemOID="ItemDef.OID.DM.STUDYID" Mandatory="Yes" OrderNumber="1" KeySequence="1" Role="Identifier"/>
    <ItemRef ItemOID="ItemDef.OID.DM.DOMAIN" Mandatory="Yes" OrderNumber="2" Role="Identifier"/>
    <ItemRef ItemOID="ItemDef.OID.DM.USUBJID" Mandatory="Yes" OrderNumber="3" KeySequence="2" Role="Identifier"/>
    <ItemRef ItemOID="ItemDef.OID.DM.SUBLJID" Mandatory="Yes" OrderNumber="4" Role="Topic"/>
    ...
  </ItemGroupDef>

  <ItemRef ItemOID="ItemDef.OID.DM.OBSOCLINIC" Mandatory="Yes" OrderNumber="10" Role="Observational"/>
  <ItemRef ItemOID="ItemDef.OID.DM.DMDTC" Mandatory="No" OrderNumber="19" Role="Timing"/>
  <ItemRef ItemOID="ItemDef.OID.DM.DMDY" Mandatory="No" OrderNumber="20" Role="Timing"/>
</ItemGroupDef>

<ItemDef OID="ItemDef.OID.DM.DMDTC" Name="DMDTC" DataType="string" Length="64" SASFieldName="DMDTC">
  Comment="Date/time of demographic data collection."/>
<ItemDef OID="ItemDef.OID.DM.DMDY" Name="DMDY" DataType="integer" Length="8" SASFieldName="DMDY">
  Comment="Study day of collection measured as integer days."/>
### SAS CLINICAL STANDARDS TOOLKIT

**SAS DATA MODEL FOR ODM**

#### TABLE: ViewTable: Srcdata.Itemgroupdefs

<table>
<thead>
<tr>
<th>OID</th>
<th>Name</th>
<th>Repeating</th>
<th>IsReferenceData</th>
<th>SASDatasetName</th>
<th>Domain</th>
</tr>
</thead>
<tbody>
<tr>
<td>ItemGroupDefs.OID.DM</td>
<td>DM</td>
<td>No</td>
<td>No</td>
<td>DM</td>
<td>DM</td>
</tr>
<tr>
<td>ItemGroupDefs.OID.AE</td>
<td>Adverse Events</td>
<td>Yes</td>
<td>No</td>
<td>AE</td>
<td>AE</td>
</tr>
<tr>
<td>ItemGroupDefs.OID.LB</td>
<td>LB</td>
<td>No</td>
<td>No</td>
<td>LB</td>
<td>LB</td>
</tr>
<tr>
<td>ItemGroupDefs.OID.labnormalran</td>
<td>Lab normal ranges</td>
<td>No</td>
<td>Yes</td>
<td>labnom</td>
<td></td>
</tr>
<tr>
<td>ItemGroupDefs.OID.mh.events</td>
<td>Medical History Event Columns</td>
<td>Yes</td>
<td>No</td>
<td>mh_evnt</td>
<td>MH</td>
</tr>
<tr>
<td>ItemGroupDefs.OID.mh.ids</td>
<td>Medical History Identifier Columns</td>
<td>No</td>
<td>No</td>
<td>mh_id</td>
<td>MH</td>
</tr>
<tr>
<td>ItemGroupDefs.OID.mh.dates</td>
<td>Medical History Timing Columns</td>
<td>Yes</td>
<td>No</td>
<td>mh_dat</td>
<td>MH</td>
</tr>
<tr>
<td>ItemGroupDefs.OID.VS</td>
<td>VS</td>
<td>Yes</td>
<td>No</td>
<td>VS</td>
<td>VS</td>
</tr>
</tbody>
</table>

#### TABLE: ViewTable: Srcdata.ItemgroupdefItemrefs

<table>
<thead>
<tr>
<th>itemOID</th>
<th>Mandatory</th>
<th>OrderNumber</th>
<th>KeySequence</th>
<th>MethodOID</th>
<th>Role</th>
<th>FK_ItemGroupDefs</th>
</tr>
</thead>
<tbody>
<tr>
<td>ItemDef.OID.DM.STUDYID</td>
<td>Yes</td>
<td>1</td>
<td>1</td>
<td></td>
<td>Identifier</td>
<td>ItemGroupDefs.OID.DM</td>
</tr>
<tr>
<td>ItemDef.OID.DM.DOMAIN</td>
<td>Yes</td>
<td>2</td>
<td>1</td>
<td></td>
<td>Identifier</td>
<td>ItemGroupDefs.OID.DM</td>
</tr>
<tr>
<td>ItemDef.OID.DM.USUBJID</td>
<td>Yes</td>
<td>3</td>
<td>2</td>
<td></td>
<td>Identifier</td>
<td>ItemGroupDefs.OID.DM</td>
</tr>
<tr>
<td>ItemDef.OID.DM.DMDTC</td>
<td>No</td>
<td>19</td>
<td>1</td>
<td></td>
<td>Timing</td>
<td>ItemGroupDefs.OID.DM</td>
</tr>
<tr>
<td>ItemDef.OID.DM.DMDY</td>
<td>No</td>
<td>20</td>
<td>1</td>
<td></td>
<td>Timing</td>
<td>ItemGroupDefs.OID.DM</td>
</tr>
</tbody>
</table>

#### TABLE: ViewTable: Srcdata.Itemdefs

<table>
<thead>
<tr>
<th>OID</th>
<th>Name</th>
<th>DataType</th>
<th>Length</th>
<th>SignificantD</th>
<th>SASFieldName</th>
<th>Origin</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>ItemDef.OID.DM.COUNTRY</td>
<td>COUNTRY</td>
<td>string</td>
<td>3</td>
<td>.</td>
<td>COUNTRY</td>
<td></td>
<td>Country of the investigational site in which the subject participated in the trial.</td>
</tr>
<tr>
<td>ItemDef.OID.DM.DMDTC</td>
<td>DMDTC</td>
<td>string</td>
<td>64</td>
<td>.</td>
<td>DMDTC</td>
<td></td>
<td>Date/time of demographic data collection.</td>
</tr>
<tr>
<td>ItemDef.OID.DM.DMDY</td>
<td>DMDY</td>
<td>integer</td>
<td>8</td>
<td>.</td>
<td>DMDY</td>
<td></td>
<td>Study day of collection measured as integer days.</td>
</tr>
</tbody>
</table>
• Reading and writing ODM XML uses an intermediate 'flat' XML Cube
• This 'flat' XML Cube can be easily transformed to
the 2-dimensional SAS data sets
<CodeList OID="CL.$AESEV" SASFormatName="$AESEV" Name="$AESEV" DataType="text">
  <CodeListItem CodedValue='1'>
    <Decode>
      <TranslatedText xml:lang="en">Mild</TranslatedText>
    </Decode>
  </CodeListItem>
  <CodeListItem CodedValue='2'>
    <Decode>
      <TranslatedText xml:lang="en">Moderate</TranslatedText>
    </Decode>
  </CodeListItem>
  <CodeListItem CodedValue='3'>
    <Decode>
      <TranslatedText xml:lang="en">Severe</TranslatedText>
    </Decode>
  </CodeListItem>
  <CodeListItem CodedValue='4'>
    <Decode>
      <TranslatedText xml:lang="en">Life Threatening</TranslatedText>
    </Decode>
  </CodeListItem>
</CodeList>
<CodeLists>
    <OID>CL.$AESEV</OID>
    <Name>$AESEV</Name>
    <DataType>text</DataType>
    <SASFormatName>$AESEV</SASFormatName>
    <FK_MetaDataVersion>MetaDataVersion.OID.1</FK_MetaDataVersion>
</CodeLists>

<CodeListItems>
    <OID>N68519</OID>
    <CodedValue>1</CodedValue>
    <FK_CodeLists>CL.$AESEV</FK_CodeLists>
    <Rank/>
</CodeListItems>

<CodeListItems>
    <OID>N68530</OID>
    <CodedValue>2</CodedValue>
    <FK_CodeLists>CL.$AESEV</FK_CodeLists>
    <Rank/>
</CodeListItems>
<CLItemDecodeTranslatedText>
  <TranslatedText>Mild</TranslatedText>
  <lang>en</lang>
  <FK_CodeListItems>N68519</FK_CodeListItems>
</CLItemDecodeTranslatedText>

<CLItemDecodeTranslatedText>
  <TranslatedText>Moderate</TranslatedText>
  <lang>en</lang>
  <FK_CodeListItems>N68530</FK_CodeListItems>
</CLItemDecodeTranslatedText>

<CLItemDecodeTranslatedText>
  <TranslatedText>Severe</TranslatedText>
  <lang>en</lang>
  <FK_CodeListItems>N68541</FK_CodeListItems>
</CLItemDecodeTranslatedText>

<CLItemDecodeTranslatedText>
  <TranslatedText>Life Threatening</TranslatedText>
  <lang>en</lang>
  <FK_CodeListItems>N68552</FK_CodeListItems>
</CLItemDecodeTranslatedText>
Consists of three distinct pieces:

- The components that are installed as part of SAS Foundation and shared files. (SAS Macros, Java JAR files, etc.)
  - `<SASROOT>\SASVersionedJarRepository\picklist`
  - `<SASROOT>\SASFoundation\9.3\cstframework\sasmacro`

- The global standards library
  - `c:\cstGlobalLibrary\`

- The global sample library
  - `c:\cstSampleLibrary\`
The **Global Standards Library** is created during installation.

A series of directories are created here:

- `/metadata` : contains data sets that have information about the registered standard versions.
- `/schema-repository` : contains schemas for XML-based standards that are supported.
- `/standards` : contains directories for each of the supported standards.
- `/xsl-repository` : contains directories and XSL files used in reading and writing XML files.
Standards
StandardSASReferences
Standardlookup
SASReferences
Properties
Messages

Validation_Master (Validation_Control)
Reference_Tables (Source_Tables)
Reference_Columns (Source_Columns)
Results
Metrics
The SASReferences data set is the “brain center” of the Toolkit. Used to tell Toolkit where things are located. Can be created by the user or generated through the Toolkit. Many users will create their own SASReferences data set.
Property files (i.e. initialize.properties) set default preferences for each process. Properties are a series of name-value pairs that are translated into global macro variables available for the duration of a Toolkit process. Invoked by the `%cst_setProperties` macro.

```
_cstDebug=0
_cstDebugOptions=mprint mlogic symbolgen mautolocdisplay
_cst_rc=0
_cst_MsgID=
_cst_MsgParm1=
_cst_MsgParm2=
_cstResultSeq=0
_cstSeqCnt=0
_cstSrcData=
_cstResultFlag=0
_cstResultsDS=work._cstresults
_cstMessages=work._cstmessages
_cstReallocateSASRefs=0
_cstFMTLibraries=work
_cstMessageOrder=APPEND
_cstSASRefsLoc=
_cstSASRefsName=
_cstSASRefs=work._cstsasrefs
```
• **Messages** data sets are used to store information about the framework and standards validation checks. There are framework messages (CST prefix) and standards validation messages (e.g. ODM prefix)

• **Results** data set. Each Toolkit process generates a results data set that can optionally be persisted beyond the SAS session based on SASReferences data set settings. Each results data set captures the outcome of specific process actions, using the messages data sets to standardize output.

• **Validation_master** contains all standard specific validation information. **Validation_control** contains study specific validation information and is created from validation_master. The “brain center” of the Toolkit validation process.
• **Reference_tables** contains ALL standard specific table information.

**Source_tables** contains study specific table/domain information and is created from reference_tables. Determines tables to be validated. For ODM, information comes from the ODM SAS Data Model.

• **Reference columns** contains all standard specific table/domain column information.

**Source_columns** contains study specific table/domain column information and is created from reference_columns. Determines columns to be validated. For ODM, information comes from the ODM SAS Data Model.
1. **Validate** and **import** an ODM 1.3.1 XML file to create a SAS data set representation

2. **Validate** the SAS data set representation of an ODM XML 1.3.1 file

3. **Extract** ClinicalData or ReferenceData SAS data sets from the SAS representation of an ODM XML 1.3.1 file

4. **Import** a CDISC/NCI ODM XML Controlled Terminology file to create a SAS data set representation

5. **Create** a SAS **format** catalog and a CTERMS SAS data set from the SAS representation of a CDISC/NCI ODM XML Controlled Terminology file
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();` (default: use WORK.SASReferences)

- Run process specific macro:
  - `%odm_xmlvalidate`
  - `%odm_read`
  - `%odm_validate`
  - `%odm_extractdomaindata`
  - `%ct_read`
  - `%odm_xmlvalidate`
  - `%ct_createformats`
• XML Validate and import an ODM 1.3.1 XML file to create a SAS data set representation

01_create_sasodm_fromxml.sas
• SAS representation of ODM 1.3.1: 76 data sets
• Keeping the non-zero data sets

```sas
proc sql noprint;
   select memname into :emptyTables separated by ' ' from sashelp.vtable
   where upcase(libname) eq "SRCDATA" and nobs eq 0;
quit;

proc datasets lib=srcdata noprint;
   delete &emptyTables;
quit;
```
• **Validate** the SAS data set representation of an ODM XML 1.3.1 file

02_validate_odm_data.sas
EXTRACTING DATA FROM ODM

- **Extract** ClinicalData or ReferenceData SAS data sets from the SAS representation of an ODM XML 1.3.1 file

**03_extract_domaindata.sas**

**04_extract_domaindata_all.sas**
<ItemDataFloat ItemOID="ID.VS.VSSTRESN">76</ItemDataFloat>
<ItemData ItemOID="ID.AE.AETERM" Value="HEADACHE" />

<table>
<thead>
<tr>
<th>OID</th>
<th>ItemOID</th>
<th>Value</th>
<th>IsNull</th>
<th>ItemDataType</th>
</tr>
</thead>
<tbody>
<tr>
<td>N80804</td>
<td>ID.VS.VSSTRESN</td>
<td>76</td>
<td></td>
<td>Float</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OID</th>
<th>ItemOID</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N80940</td>
<td>ID.AETERM</td>
<td>HEADACHE</td>
</tr>
</tbody>
</table>
<ClinicalData StudyOID="TRIALXYZ" MetaDataVersionOID="SDTM 3.1.2">
  <SubjectData SubjectKey="01-715-1085">
    <StudyEventData StudyEventOID="SE.MyEvent.LB" StudyEventRepeatKey="1">
      <FormData FormOID="F.LB" FormRepeatKey="1">
        <ItemGroupData ItemGroupOID="IG.LB" ItemGroupRepeatKey="1">
          <ItemData ItemOID="ID.STUDYID" Value="CDISCPILLOT01" />
          <ItemData ItemOID="ID.DOMAIN" Value="LB" />
          <ItemData ItemOID="ID.USUBJID" Value="01-715-1085" />
          <ItemData ItemOID="ID.LBSEQ" Value="1" />
          <ItemData ItemOID="ID.LBTESTCD" Value="ALB" />
          <ItemData ItemOID="ID.LBTEST" Value="Albumin" />
          <ItemData ItemOID="ID.LBCAT" Value="CHEMISTRY" />
          <ItemData ItemOID="ID.LBORRES" Value="4.1" />
          <ItemData ItemOID="ID.LBORRESU" Value="g/dL" />
        </ItemGroupData>
      </FormData>
    </StudyEventData>
  </SubjectData>
</ClinicalData>
### EXTRACTING DATA

#### VIEWTABLE: Ssrcdata.Itemgroupdefs

<table>
<thead>
<tr>
<th>OID</th>
<th>Name</th>
<th>Repeating</th>
<th>IsReferenceData</th>
<th>SASDatasetName</th>
<th>Domain</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IG.LB</td>
<td>Yes</td>
<td></td>
<td>LB</td>
<td>LB</td>
</tr>
<tr>
<td>2</td>
<td>IG.labnormalranges</td>
<td>No</td>
<td>Yes</td>
<td>labnom</td>
<td></td>
</tr>
</tbody>
</table>

#### VIEWTABLE: Ssrcdata.Itemdefs

<table>
<thead>
<tr>
<th>OID</th>
<th>Name</th>
<th>DataType</th>
<th>Length</th>
<th>SignificantDigits</th>
<th>SASFieldName</th>
<th>CodeListRef</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ID.STUDYID</td>
<td>text</td>
<td>12</td>
<td></td>
<td>. STUDYID</td>
<td>CodeLists.OID.LBTESTCD</td>
</tr>
<tr>
<td>2</td>
<td>ID.DOMAIN</td>
<td>text</td>
<td>2</td>
<td></td>
<td>. DOMAIN</td>
<td>CodeLists.OID.LBTESTCD</td>
</tr>
<tr>
<td>3</td>
<td>ID.USUBJID</td>
<td>text</td>
<td>11</td>
<td></td>
<td>. USUBJID</td>
<td>CodeLists.OID.LBTESTCD</td>
</tr>
<tr>
<td>4</td>
<td>ID.LBSEQ</td>
<td>float</td>
<td>12</td>
<td>2</td>
<td>2 LBSEQ</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>ID.LBTESTCD</td>
<td>text</td>
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</tr>
<tr>
<td>6</td>
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</tr>
<tr>
<td>7</td>
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<td>. LBCAT</td>
<td></td>
</tr>
<tr>
<td>8</td>
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<td>text</td>
<td>5</td>
<td></td>
<td>. LBORRES</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>ID.LBORRESU</td>
<td>text</td>
<td>8</td>
<td></td>
<td>. LBORRESU</td>
<td></td>
</tr>
</tbody>
</table>

#### VIEWTABLE: Ssrcdata.Itemdata

<table>
<thead>
<tr>
<th>OID</th>
<th>ItemOID</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>N77116</td>
<td>CDISCPILOT01</td>
</tr>
<tr>
<td>22</td>
<td>N77120</td>
<td>LB</td>
</tr>
<tr>
<td>23</td>
<td>N77124</td>
<td>01-715-1085</td>
</tr>
<tr>
<td>24</td>
<td>N77128</td>
<td>1</td>
</tr>
<tr>
<td>25</td>
<td>N77132</td>
<td>ALB</td>
</tr>
<tr>
<td>26</td>
<td>N77136</td>
<td>Albumin</td>
</tr>
<tr>
<td>27</td>
<td>N77140</td>
<td>CHEMISTRY</td>
</tr>
<tr>
<td>28</td>
<td>N77144</td>
<td>4.1</td>
</tr>
<tr>
<td>29</td>
<td>N77148</td>
<td>g/dL</td>
</tr>
</tbody>
</table>
%odm_extractdomaindata(
  _cstSourceMetaData=srcdata,
  _cstSourceData=srcdata,
  _cstIsReferenceData=No,
  _cstSelectAttribute=SASDataSetName,
  _cstSelectAttributeValue=LB,
  _cstLang=,
  _cstMaxLabelLength=256,
  _cstAttachFormats=Yes,
  _cstODMMinimumKeyset=No,
  _cstOutputLibrary=trgdata,
  _cstOutputDS=LB
);
filename incCode CATALOG "work._cstCode.domains.source" LRECL=255;

data _null_;  
set srcdata.itemgroupdefs(keep=OID Name IsReferenceData SASDatasetName Domain);
  file incCode;
  length macrocall $400 _cstOutputName $100;

  _cstOutputName=SASDatasetName;
  * If we have to use the Name, Only use letters and digits;
  if missing(_cstOutputName) then _cstOutputName=cats(compress(Name, 'adk'));
  * If first character a digit, prepend an underscore;
  if anydigit(_cstOutputName)=1 then _cstOutputName=cats('_', _cstOutputName);
  * Cut long names;
  if length(_cstOutputName) > 32 then _cstOutputName=substr(_cstOutputName, 1, 32);

  macrocall=cats('%odm_extractdomaindata(_cstSelectAttribute=OID, 
                     , _cstSelectAttributeValue='', OID, 
                     , _cstIsReferenceData='', IsReferenceData, 
                     , _cstMaxLabelLength=256', 
                     , _cstAttachFormats=Yes', 
                     , _cstODMMinimumKeyset=No', 
                     , _cstLang=en', 
                     , _cstOutputDS='', _cstOutputName, '');

  put macrocall;
run;

%include incCode;
IMPORTING CONTROLLED TERMINOLOGY

- Import a CDISC/NCI ODM XML Controlled Terminology file to create a SAS data set representation
## Importing Controlled Terminology

<table>
<thead>
<tr>
<th>Code</th>
<th>Codelist Code</th>
<th>Codelist Extensible (Yes/No)</th>
<th>Codelist Name</th>
<th>CDISC Submission Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>C66767</td>
<td>No Action Taken with Study Treatment</td>
<td>ACN</td>
<td>Action Taken with Study Treatment</td>
<td></td>
</tr>
<tr>
<td>C49503</td>
<td>C66767</td>
<td>Action Taken with Study Treatment</td>
<td>DOSE INCREASED</td>
<td>An increased dose in the frequency, strength or amount. (NCI): Dose Increased</td>
</tr>
<tr>
<td>C49504</td>
<td>C66767</td>
<td>Action Taken with Study Treatment</td>
<td>DOSE NOT CHANGED</td>
<td></td>
</tr>
<tr>
<td>Changed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C49505</td>
<td>C66767</td>
<td>Action Taken with Study Treatment</td>
<td>DOSE REDUCED</td>
<td>An reduced dose in the frequency, strength or amount. (NCI): Dose Reduced</td>
</tr>
<tr>
<td>C49501</td>
<td>C66767</td>
<td>Action Taken with Study Treatment</td>
<td>DRUG INTERRUPTED</td>
<td>Terminating a prescribed regimen of medication. (NCI): Drug Interrupted</td>
</tr>
<tr>
<td>C49502</td>
<td>C66767</td>
<td>Action Taken with Study Treatment</td>
<td>DRUG WITHDRAWN</td>
<td>An interrupted prescribed regimen of medication. (NCI): Drug Withdrawn</td>
</tr>
<tr>
<td>C48660</td>
<td>C66767</td>
<td>Action Taken with Study Treatment</td>
<td>NOT APPLICABLE NA; Not Applicable Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Not Applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C17998</td>
<td>C66767</td>
<td>Action Taken with Study Treatment</td>
<td>UNKNOWN U; Unknown Not known</td>
<td>Outcome of Event OUT Outcome of Event</td>
</tr>
<tr>
<td>C66768</td>
<td>No</td>
<td></td>
<td></td>
<td>A condition or the adverse event. (NCI): CDISC SDTM Adverse Event Outcome Terminology</td>
</tr>
<tr>
<td>C48275</td>
<td>C66768</td>
<td>Outcome of Event</td>
<td>FATAL Grade 5; 5; FATAL</td>
<td>The termination has not improved or recuperated. (NCI): Not Recovered or Not Resolved</td>
</tr>
<tr>
<td>C49494</td>
<td>C66768</td>
<td>Outcome of Event</td>
<td>NOT RECOVERED/NOT RESOLVED</td>
<td>One of improved or recuperated. (NCI): Recovered or Resolved</td>
</tr>
<tr>
<td>C49498</td>
<td>C66768</td>
<td>Outcome of Event</td>
<td>RECOVERED/RESOLVED</td>
<td>One of the post improved or recuperated. (NCI): Recovered or Resolved</td>
</tr>
<tr>
<td>C49495</td>
<td>C66768</td>
<td>Outcome of Event</td>
<td>RECOVERED/RESOLVED WITH SEQUELAE</td>
<td></td>
</tr>
</tbody>
</table>
## Importing Controlled Terminology

<table>
<thead>
<tr>
<th>Code</th>
<th>CodeList Code</th>
<th>CodeList Name</th>
<th>CDISC Submission Value</th>
<th>CDISC Synonym(s)</th>
<th>CDISC Definition</th>
<th>NCI Preferred Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>C66767</td>
<td>No</td>
<td>Action Taken with Study Treatment</td>
<td>ACN</td>
<td>Action Taken with Study Treatment</td>
<td>An indication that a medication schedule was modified by addition, either by changing the frequency, strength or amount. (NCI)</td>
<td>CDISC SDTM Action Taken with Study Terminology</td>
</tr>
<tr>
<td>C45503</td>
<td></td>
<td>Action Taken with Study Treatment</td>
<td>DOSE INCREASED</td>
<td></td>
<td>Dose Increased</td>
<td></td>
</tr>
<tr>
<td>C45504</td>
<td></td>
<td>Action Taken with Study Treatment</td>
<td>DOSE NOT CHANGED</td>
<td></td>
<td>Dose Not Changed</td>
<td></td>
</tr>
<tr>
<td>C45505</td>
<td></td>
<td>Action Taken with Study Treatment</td>
<td>DOSE REDUCED</td>
<td></td>
<td>Dose Reduced</td>
<td></td>
</tr>
<tr>
<td>C45501</td>
<td></td>
<td>Action Taken with Study Treatment</td>
<td>DRUG INTERRUPTED</td>
<td></td>
<td>An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)</td>
<td>Drug Interrupted</td>
</tr>
<tr>
<td>C45502</td>
<td></td>
<td>Action Taken with Study Treatment</td>
<td>DRUG WITHDRAWN</td>
<td></td>
<td>Drug Withdrawn</td>
<td></td>
</tr>
<tr>
<td>C66767</td>
<td></td>
<td>Action Taken with Study Treatment</td>
<td>NOT APPLICABLE</td>
<td>NA</td>
<td>Determination of a value is not relevant in the current context. (NCI)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>C17999</td>
<td></td>
<td>Action Taken with Study Treatment</td>
<td>UNKNOWN</td>
<td>U; Unknown</td>
<td>Not known, not observed, not recorded, or refused. (NCI)</td>
<td>Unknown</td>
</tr>
<tr>
<td>C66758</td>
<td>No</td>
<td>Outcome of Event</td>
<td>OUT</td>
<td>Outcome of Event</td>
<td>A condition or event that is attributed to the adverse event and is the result or conclusion of the adverse event. (NCI)</td>
<td>CDISC SDTM Adverse Event Outcome Terminology</td>
</tr>
<tr>
<td>C45525</td>
<td></td>
<td>Outcome of Event</td>
<td>FATAL</td>
<td></td>
<td>The termination of life as a result of an adverse event. (NCI)</td>
<td>Death Related to Adverse Event</td>
</tr>
<tr>
<td>C45449</td>
<td></td>
<td>Outcome of Event</td>
<td>NOT RECOVERED/NOT RESOLVED</td>
<td></td>
<td>One of the possible results of an adverse event outcome that indicates that the event has not improved or resolved. (NCI)</td>
<td>Not Recovered or Not Resolved</td>
</tr>
<tr>
<td>C45499</td>
<td></td>
<td>Outcome of Event</td>
<td>RECOVERED/RESOLVED</td>
<td></td>
<td>One of the possible results of an adverse event outcome that indicates that the event has improved or resolved. (NCI)</td>
<td>Recovered or Resolved</td>
</tr>
<tr>
<td>C45495</td>
<td></td>
<td>Outcome of Event</td>
<td>RECOVERED/RESOLVED WITH SEQUELAE</td>
<td></td>
<td>One of the possible results of an adverse event outcome where the subject recovered but retained pathological conditions resulting from the prior disease or injury. (NCI)</td>
<td>Recovered or Resolved with Sequelae</td>
</tr>
<tr>
<td>C45496</td>
<td></td>
<td>Outcome of Event</td>
<td>RECOVERING/RESOLVING</td>
<td></td>
<td>One of the possible results of an adverse event outcome that indicates that the event is improving. (NCI)</td>
<td>Recovering or Resolving</td>
</tr>
<tr>
<td>C17999</td>
<td></td>
<td>Outcome of Event</td>
<td>UNKNOWN</td>
<td>U; Unknown</td>
<td>Not known, not observed, not recorded, or refused. (NCI)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Code</td>
<td>CodeList Code</td>
<td>CodeList Extensible</td>
<td>CodeList Name</td>
<td>CDISC Submission Value</td>
<td>CDISC Synonym(s)</td>
<td>CDISC Definition</td>
</tr>
<tr>
<td>-------</td>
<td>---------------</td>
<td>---------------------</td>
<td>--------------------------------------</td>
<td>------------------------</td>
<td>--------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>C86783</td>
<td>No</td>
<td>Severity/Intensity Scale for Adverse Events</td>
<td>AESEV</td>
<td>Severity/Intensity Scale for Adverse Events</td>
<td>A scale that defines the degree or state of disease existing in a patient as a result of the occurrence of an adverse event. (NCT)</td>
<td>CDISC SDTM Severity/Intensity Scale for Adverse Event Terminology</td>
</tr>
<tr>
<td>C41338</td>
<td>C66789</td>
<td>Severity/Intensity Scale for Adverse Events</td>
<td>MILD</td>
<td>Grade 1; 1</td>
<td>A type of adverse event that is usually transient and may require only minimal treatment or therapeutic intervention. The event does not generally interfere with usual activities of daily living.</td>
<td>Mild Adverse Event</td>
</tr>
<tr>
<td>C41339</td>
<td>C66789</td>
<td>Severity/Intensity Scale for Adverse Events</td>
<td>MODERATE</td>
<td>Grade 2; 2</td>
<td>A type of adverse event that is usually alleviated with additional specific therapeutic intervention. The event interferes with usual activities of daily living, causing discomfort but poses no significant or permanent risk of harm to the research participant.</td>
<td>Moderate Adverse Event</td>
</tr>
<tr>
<td>C41340</td>
<td>C66789</td>
<td>Severity/Intensity Scale for Adverse Events</td>
<td>SEVERE</td>
<td>Grade 3; 3</td>
<td>A type of adverse event that interrupts usual activities of daily living, or significantly affects clinical status, or may require intensive therapeutic intervention.</td>
<td>Severe Adverse Event</td>
</tr>
</tbody>
</table>

```xml
<?xml version="1.0" encoding="utf-8"?>
<CodeList OID="CL.C66789.AESEV" Name="Severity/Intensity Scale for Adverse Events" Data-type="text" nci:ExtCodeID="C66789" nci:CodeListExtensible="No">
  <Description>
    <TranslatedText xml:lang="en">A scale that defines the degree or state of disease existing in a patient as a result of the occurrence of an adverse event. (NCI)</TranslatedText>
  </Description>
  - <EnumeratedItem CodedValue="MILD" nci:ExtCodeID="C41338">
    <nci:CDISCSynonym>Grade 1</nci:CDISCSynonym>
    <nci:CDISCSynonym>1</nci:CDISCSynonym>
    <nci:CDISCDefinition>A type of adverse event that is usually transient and may require only minimal treatment or therapeutic intervention. The event does not generally interfere with usual activities of daily living.</nci:CDISCDefinition>
    <nci:PreferredTerm>Mild Adverse Event</nci:PreferredTerm>
  </EnumeratedItem>
  - <EnumeratedItem CodedValue="MODERATE" nci:ExtCodeID="C41339">
    <nci:CDISCSubmissionValue>AESEV</nci:CDISCSubmissionValue>
    <nci:CDISCSynonym>Severity/Intensity Scale for Adverse Events</nci:CDISCSynonym>
    <nci:PreferredTerm>CDISC SDTM Severity/Intensity Scale for Adverse Event Terminology</nci:PreferredTerm>
  </EnumeratedItem>
</CodeList>
```
IMPORTING CONTROLLED TERMINOLOGY

- **Import** a CDISC/NCI ODM XML Controlled Terminology file to create a SAS data set representation

  05_create_sasct_fromxml_sdtm.sas

  06_create_sasct_fromxml_qs.sas
IMPORTING CONTROLLED TERMINOLOGY

- **Import** a CDISC/NCI ODM XML Controlled Terminology file to create a SAS data set representation

05_create_sasct_fromxml_sdtm.sas
06_create_sasct_fromxml_qs.sas
• **Create** a SAS format catalog and a CTERMS SAS data set from the SAS representation of an CDISC/NCI ODM XML Controlled Terminology file

07_create_ctformats_sdtm.sas
08_create_ctformats_qs.sas
<CodeList OID="CL.C66784.TOXGRV3" Name="Common Terminology Criteria for Adverse Events"
          DataType="text" nciom:ExtCodeID="C66784" nciom:CodeListExtensible="No">
  <Description>
    <TranslatedText xml:lang="en">A standard terminology developed to report adverse
    events occurring in cancer clinical trials. Common terminology criteria for adverse events
    (CTCAE) are used in study adverse event summaries and Investigational New Drug reports
    to the Food and Drug Administration. The CTCAE contain a grading scale for each
    adverse event term representing the severity of the event. (NCI)</TranslatedText>
  </Description>
  <EnumeratedItem CodedValue="1" nciom:ExtCodeID="C41338">
    <nciom:CDISCsynonym>Grade 1</nciom:CDISCsynonym>
    <nciom:CDISCsynonym>1</nciom:CDISCsynonym>
    <nciom:CDISCdefinition>A type of adverse event that is usually transient and may require only</nciom:CDISCdefinition>
    <nciom:PreferredTerm>Mild Adverse Event</nciom:PreferredTerm>
  </EnumeratedItem>
  <EnumeratedItem CodedValue="2" nciom:ExtCodeID="C41339"> [5 lines]
  <EnumeratedItem CodedValue="3" nciom:ExtCodeID="C41340"> [5 lines]
  <EnumeratedItem CodedValue="4" nciom:ExtCodeID="C41337"> [6 lines]
  <EnumeratedItem CodedValue="5" nciom:ExtCodeID="C48275"> [6 lines]
  <nciom:CDISCSubmissionValue>TOXGRV3</nciom:CDISCSubmissionValue>
  <nciom:CDISCsynonym>Common Terminology Criteria for Adverse Events V3.0</nciom:CDISCsynonym>
  <nciom:PreferredTerm>CDISC SDTM Common Terminology Criteria for Adverse Event Grade Terminology
  </EnumerisedList>
CDISCSubmissionValue (TOXGRV3)

→ valid SAS Format name

* An F will be appended to CodeList Submission Values that end with a digit;

```sas
%ct_createformats(
   _cstLang=en,
   _cstCreateCatalog=1,
   _cstKillCatFirst=1,
   _cstUseExpression=,
   _cstAppendChar=F,
   _cstDeleteEmptyColumns=1,
   _cstTrimCharacterData=1
);
```
CDISCSubmissionValue (TOXGRV3) 
→ valid SAS Format name

* Alternatively a custom format can be used to map CodeList Submission Values to valid SAS format names;

```sas
proc format lib=work.formats;
  value $_tox
    "TOXGRV3" = "TOXGRV3F"
    "TOXGRV4" = "TOXGRV4F"
;
run;

%ct_createformats(
   _cstLang=en,
   _cstKillCatFirst=1,
   _cstUseExpression=%str(strip(put(cdiscsubmissionvalue, $_tox32.)))
);
```
CDISCSubmissionValue (TOXGRV3)

→ valid SAS Format name
THANK YOU!

QUESTIONS?