SAS® Clinical Standards Toolkit 1.7.1: What's New

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Prepared by: CST Development Team
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<CST Global Library>\metadata
There were updates to metadata files to implement Analysis Results Metadata v1.0 for Define-XML 2.0:

- Standards data set
- Standardlookup data set
- availabletransforms.xml

**Note:** Since this hotfix will need to overwrite the existing files in the <Global Library>\metadata folder, the customer may need to update the Global Standards Library to include any prior customizations and to register the desired default versions of each standard.

Framework Macros
There were updates to Framework macros related to Validation. More information in the results data set and the log was provided when validation checks cannot be run because of sublist problems.

- cstcheck_column
- cstcheck_columnncmpare
- cstcheck_columnvarlist
- cstcheck_notconsistent
- cstcheck_notincodelist
- cstutil_buildcollist
- cstutil_builddomlist

Also, there were minor fixes in:

- cstutilcheckjava
- cstutilmanagecolumnsize

**ODM 1.3.0 and ODM 1.3.1**
Updates to ItemData.xsl to fix an issue with Measurement Units not being imported correctly. This also came with an update to the validation control data sets: validation_control and validation_master. Sample ODM XML files and sample data set representations were changed for this update as well.
Small syntax update to sample drivers: `extract_domaindata_all.sas` and `extract_domaintemplates_all.sas`

**Dataset-XML**
Small fixes to `datasetxml_read`, `datasetxml_write` and `datasetxml_createmap` macros.

**Controlled Terminology**
ADaM Controlled Terminology 2015-12 was added to the `cdisc-ct-1.0.0` and `cdisc-terminoloy` in CST.

**SDTM 3.2**
Unbalanced quotes and parentheses fixed in `reference_columns` metadata.

**Define-XML 2.0**

**Templates**
- Added new template: `studyanalysisresultmetadata` (label='Source Analysis Results Metadata')
- Added columns to `studycolumnmetadata`:
  - `displayidentifier` char(128) label='Analysis Display Identifier'
  - `resultidentifier` char(128) label='Analysis Display Result Identifier'
- Changed `studycolumnmetadatadoctype` label: 'Document Type (CRF/COMMENT/METHOD)'
- Changed lengths:
  - `studycolumnmetadataxmldatatype`: 8 → 18
  - `studycolumnmetadataorigindescription`: 40 → 1000
  - `studyvaluemetadataxmldatatype`: 8 → 18
- Deleted `studyvaluemetadatavalue`
- Added column to `studyvaluemetadata`:
  - `origindescription` char(1000) label='Column Origin Description'

Since these templates are used to create `source_*` data set, these changes will impact the structure of these `source_*` datasets

**Internal model data sets:**
- **New:**
  - `analysisdataset`
  - `analysisdatasets`
  - `analysisdocumentation`
  - `analysisprogrammingcode`
  - `analysisresultdisplays`
- analysisresults
- analysisvariables
- analysiswhereclauserefs

- Updated:
  - in several data sets the lengths were updated

XML Schema Validation

Define-XML v2.0 are now validated against: `<CST Global Library>\schema-repository\cdisc-arm-1.0\arm1-0-0.xsd`

This means a change in `<CST Global Library>\metadata\availabletransforms.xml` and `standards.schema`

The cdisc-arm-1.0 folder was added to: `<CST Global Library>\schema-repository`

Transformation Stylesheets:

Additions and updates to: `<CST Global Library>\xsl-repository\DEFINE-XML\2.0.0`

New Display Stylesheet:

`<CST Global Library>\standards\cdisc-definexml-2.0.0-1.7\stylesheet\define2-0-0.xsl`

New Map:

`<CST Sample Library>\cdisc-definexml-2.0.0-1.7\referencexml\define.map`

Sample Drivers:

- **New:** `create_definexml_from_source_adam.sas`
- **Updated:** all the other ones, mostly cosmetic. Macro parameters were added, where applicable to implement ARM.
  - Added `_cstCheckLengths=Y to %define_sourcetodefine macrocalls`
  - Added `_cstSourceAnalysisResults=sampdata.source_analysisresults or _cstTrgAnalysisResultDS=trgmeta.source_analysisresults` to several macros to create `source_analysisresults` data set
  - Several changes to `migrate_crtdds_to_definexml_sdtm.sas` and `migrate_crtdds_to_definexml_adam.sas`
Updated sample data sets (cdisc-adam-2-1 and cdisc-sdtm-3.1.2):

- <CST Sample Library>\cdisc-definexml-2.0.0-1.7\data
- <CST Sample Library>\cdisc-definexml-2.0.0-1.7\deriveddata
- <CST Sample Library>\cdisc-definexml-2.0.0-1.7\derivedmetadata
- <CST Sample Library>\cdisc-definexml-2.0.0-1.7\derivestudymetadata_crtdds
- <CST Sample Library>\cdisc-definexml-2.0.0-1.7\derivestudymetadata_define
- <CST Sample Library>\cdisc-definexml-2.0.0-1.7\derivestudymetadata_saslib
- <CST Sample Library>\cdisc-definexml-2.0.0-1.7\metadata
- <CST Sample Library>\cdisc-definexml-2.0.0-1.7\results
- <CST Sample Library>\cdisc-definexml-2.0.0-1.7\sascstdemodata\metadata

New Macros:

- define_sourceanalysisresults.sas
- defineutil_splitwhereclause.sas
- defineutil_validatelengths.sas
- defineutil_validatewhereclause.sas

Detailed macro changes:

**definecreatesrcmetadefinedefine.sas**

- Added _cstTrgAnalysisResultDS= parameter
- The macro will – optionally - create the Analysis Results Metadata data set as specified in the _cstTrgAnalysisResultDS parameter

**definecreatesrcmetadefinesaslib.sas**

- Added _cstTrgAnalysisResultDS= parameter
- The macro will – optionally - create the Analysis Results Metadata data set (0 observations) as specified in the _cstTrgAnalysisResultDS parameter

**cstutilgetncimetadata.sas**

- Minor changes related to _cstDebug

**cstutilmigratecrtdds2define.sas**
• Added parameters: _cstSrcType= and _cstStandardVersion
• Will now create Analysis Results Metadata data set when _cstSrcType=analysisresult
The resulting data set is very much an initial source dataset, since the existing source
metadata dataset that was in CST (C:\cstSampleLibrary\cdisc-adam-2.1-
1.7\sascstdemodata\metadata\analysis_results.sas7bdat) is very insufficient)

define_sourcetodefine.sas
• Added parameters: _cstSourceAnalysisResults= and _cstCheckLengths=N
• Macro calls to %define_source<xxxx> macros updated with _cstCheckLengths and other
new applicable parameters.

define_sourcestudy.sas
• Added parameter: _cstCheckLengths=N
• Changed NAME and DESCRIPTION values in output MetaDataVersion data set

define_sourcetables.sas
• Added parameter: _cstCheckLengths=N

define_sourcecolumns.sas
• Added parameter: _cstCheckLengths=N

define_sourcecodelists.sas
• Added parameters: _cstSourceTables= and _cstCheckLengths=N

define_sourcevalues.sas
• Added parameters: _cstSourceTables=, _cstSourceColumns and _cstCheckLengths=N
• Added call to %defineutil_validatewhereclause macro
• Replaced code with call to %defineutil_splitwhereclause macro

define_sourcedocuments.sas
• Added parameters: _cstSourceTables=, _cstSourceColumns, _cstSourceAnalysisResults and
_cstCheckLengths=N
• Substantial changes to the macro.
• source_documents.DOCTYPE has new values: "SUPPDOC", "DISPLAY", "RESULTDOC",
"RESULTCODE"
• Better validation of source_documents.PDFPAGEREFS

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