

# Two-way Ticket, Please... All aboard the SAS® Clinical Standards Toolkit 1.5 Express

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## Define XML

To extract the metadata from the define.xml, submit the create\_sascrtdds\_fromxml.sas driver program. This driver program reads the define.xml file and generates the SAS representation of the CRT-DDS model using the crtdds\_read.sas macro. This driver program generates the source\_tables and source\_columns data sets in the library specified in the sasreferences data set.

Located here: C:\cstSampleLibrary\cdisc-crtdds-1.0-1.5\programs

Name	Date modified	Type	Size
create_crtdds_define.sas	8/28/2013 11:51 AM	SAS System Program	10 KB
create_crtdds_define_adam.sas	8/28/2013 11:51 AM	SAS System Program	10 KB
create_crtdds_define_pdf.sas	8/28/2013 11:51 AM	SAS System Program	10 KB
create_crtdds_define_pdf_adam.sas	8/28/2013 11:51 AM	SAS System Program	10 KB
create_crtdds_from_adam.sas	8/28/2013 11:51 AM	SAS System Program	11 KB
create_crtdds_from_sdtm.sas	8/28/2013 11:51 AM	SAS System Program	12 KB
create_sascrtdds_fromxml.sas	8/28/2013 11:51 AM	SAS System Program	13 KB
import_sascrtdds_fromxml_export_toxml.sas	8/28/2013 11:51 AM	SAS System Program	10 KB
validate_crtdds_data.sas	8/28/2013 11:51 AM	SAS System Program	12 KB
validate_crtdds_data_adam.sas	8/28/2013 11:51 AM	SAS System Program	12 KB

The above step generates the source\_tables and source\_columns in the following directory specified in the sasreferences data set which is C:\cstSampleLibrary\cdisc-crtdds-1.0-1.5\derivedmetadata.

Name	Date modified	Type	Size
source_columns.sas7bdat	8/28/2013 11:51 AM	SAS Data Set	576 KB
source_study.sas7bdat	8/28/2013 11:51 AM	SAS Data Set	320 KB
source_tables.sas7bdat	8/28/2013 11:51 AM	SAS Data Set	144 KB

Source metadata that describes the SDTM domains and columns is derived using information contained in the CRT-DDS data sets derived above. Submit the create\_sourcemetadatas.sas SDTM driver program. For SDTM 3.1.3, it is installed in the sample study library directory/ cdisc-sdtm-3.1.3-1.5\sascstdemodata\programs directory. In this exercise, this driver program calls the sdtmutil\_createscmetadatas macro, which uses a library of SAS data sets that capture define.xml metadata (typically derived using the crtdds\_read macro). The output of this step is a set of SDTM metadata in source\_tables, source\_columns, and source\_study data sets.

Name	Date modified	Type	Size
create_formatsfromcrtdds.sas	8/28/2013 11:48 AM	SAS System Program	13 KB
create_sasdatafromcpt.sas	8/28/2013 11:48 AM	SAS System Program	13 KB
create_sourcemetadatas.sas	8/28/2013 11:48 AM	SAS System Program	19 KB
cst_metadatareport.sas	8/28/2013 11:48 AM	SAS System Program	15 KB
cst_report.sas	8/28/2013 11:48 AM	SAS System Program	15 KB
validate_data.sas	8/28/2013 11:48 AM	SAS System Program	15 KB

The above step generates the source\_tables and source\_columns in the following directory specified in the sasreferences data set which is C:\cstSampleLibrary\cdisc-sdtm-3.1.3-1.5\sascstdemodata\derived\metadata.

Name	Date modified	Type	Size
source_columns.sas7bdat	8/30/2013 11:07 AM	SAS Data Set	5,376 KB
source_documents.sas7bdat	8/30/2013 11:07 AM	SAS Data Set	512 KB
source_study.sas7bdat	8/30/2013 11:07 AM	SAS Data Set	504 KB
source_tables.sas7bdat	8/30/2013 11:07 AM	SAS Data Set	768 KB
source_values.sas7bdat	8/30/2013 11:07 AM	SAS Data Set	512 KB

SAS formats that support SDTM controlled terminology are derived using information contained in the CRT-DDS data sets that were derived in the first step above. Submit the create\_formatsfromcrtdds.sas SDTM driver program. For SDTM 3.1.3, this program is installed in the sample study library directory/ cdisc-sdtm-3.1.3-1.5\sascstdemodata\programs directory. The driver program accesses the sdtmutil\_createformatsfromcrtdds macro and generates the controlled terminology SAS formats catalog based on codelists specified in the define.xml file.

Name	Date modified	Type	Size
create_formatsfromcrtdds.sas	8/28/2013 11:48 AM	SAS System Program	13 KB
create_sasdatafromcpt.sas	8/28/2013 11:48 AM	SAS System Program	13 KB
create_sourcemetadatas.sas	8/28/2013 11:48 AM	SAS System Program	19 KB
cst_metadatareport.sas	8/28/2013 11:48 AM	SAS System Program	15 KB
cst_report.sas	8/28/2013 11:48 AM	SAS System Program	15 KB
validate_data.sas	8/28/2013 11:48 AM	SAS System Program	15 KB

The above step generates the source\_tables and source\_columns in the following directory specified in the sasreferences data set which is C:\cstSampleLibrary\cdisc-sdtm-3.1.3-1.5\sascstdemodata\derived\formats.

Name	Date modified	Type	Size
ctterms.sas7bcat	8/30/2013 11:31 AM	SAS Catalog	381 KB

At the end of this process Clinical Standards Toolkit 1.5 has successfully read a define.xml and placed the metadata in the proper data sets:  
 source\_columns - containing SDTM domain column metadata  
 source\_tables - containing SDTM domain table metadata  
 source\_study - containing Study level metadata  
 source\_values - containing value level metadata  
 source\_documents - containing document metadata  
 cterms format catalog

Access a study that contains valid CDISC SDTM data and metadata. This is a study that contains domain data (AE, DM, CO, and so on) and the SAS Clinical Standards Toolkit metadata about that SDTM study, such as source\_tables and source\_columns. The SAS Clinical Standards Toolkit also includes XSL style sheets, XML map files, and any metadata that is provided by SAS during the SAS Clinical Standards Toolkit installation.

For the Clinical Standards Toolkit the source data is located at: <cstSampleLibrary>\cdisc-sdtm-3.1.3-1.5\sascstdemodata\data

Name	Date modified	Type	Size
ae.sas7bdat	8/28/2013 11:48 AM	SAS Data Set	516 KB
ce.sas7bdat	8/28/2013 11:48 AM	SAS Data Set	232 KB
cm.sas7bdat	8/28/2013 11:48 AM	SAS Data Set	384 KB
co.sas7bdat	8/28/2013 11:48 AM	SAS Data Set	128 KB

and the study metadata is located at <cstSampleLibrary>\cdisc-sdtm-3.1.3-1.5\sascstdemodata\metadata.

Name	Date modified	Type	Size
source_columns.sas7bdat	8/28/2013 11:48 AM	SAS Data Set	3,072 KB
source_documents.sas7bdat	8/28/2013 11:48 AM	SAS Data Set	512 KB
source_study.sas7bdat	8/28/2013 11:48 AM	SAS Data Set	504 KB
source_tables.sas7bdat	8/28/2013 11:48 AM	SAS Data Set	304 KB
source_values.sas7bdat	8/28/2013 11:48 AM	SAS Data Set	496 KB

Use the set of sample driver programs that are provided in the SAS Clinical Standards Toolkit to define the input and output files for each process task and to invoke the macros that support each standard-specific task. The driver programs are designed to run with the sample studies but can be modified as needed. New custom drivers can also be created and used. These macros are located in <cstSampleLibrary>\cdisc-crtdds-1.0-1.5\programs directory.

Name	Date modified	Type	Size
create_crtdds_define.sas	8/28/2013 11:51 AM	SAS System Program	10 KB
create_crtdds_define_adam.sas	8/28/2013 11:51 AM	SAS System Program	10 KB
create_crtdds_define_pdf.sas	8/28/2013 11:51 AM	SAS System Program	10 KB
create_crtdds_define_pdf_adam.sas	8/28/2013 11:51 AM	SAS System Program	10 KB
create_crtdds_from_adam.sas	8/28/2013 11:51 AM	SAS System Program	11 KB
create_crtdds_from_sdtm.sas	8/28/2013 11:51 AM	SAS System Program	12 KB
create_sascrtdds_fromxml.sas	8/28/2013 11:51 AM	SAS System Program	13 KB
import_sascrtdds_fromxml_export_toxml.sas	8/28/2013 11:51 AM	SAS System Program	10 KB
validate_crtdds_data.sas	8/28/2013 11:51 AM	SAS System Program	12 KB
validate_crtdds_data_adam.sas	8/28/2013 11:51 AM	SAS System Program	12 KB

Submit the create\_crtdds\_fromsdtm.sas driver program to access the crtdds\_sdtmtoxml macro, and create the 39 data sets that comprise the SAS representation of the CRT-DDS model. These 39 output data sets are written to the <cstSampleLibrary>\cdisc-crtdds-1.0-1.5\data directory.

Name	Date modified	Type	Size
annotatedcrfs.sas7bdat	8/28/2013 11:51 AM	SAS Data Set	360 KB
clitemdecodetranslatedtext.sas7bdat	8/28/2013 11:51 AM	SAS Data Set	9,408 KB
codelistitems.sas7bdat	8/28/2013 11:51 AM	SAS Data Set	3,456 KB
codeliststxt.sas7bdat	8/28/2013 11:51 AM	SAS Data Set	128 KB
computationmethods.sas7bdat	8/28/2013 11:51 AM	SAS Data Set	360 KB
definedocument.sas7bdat	8/28/2013 11:51 AM	SAS Data Set	512 KB

Validate the CRT-DDS data sets by submitting the validate\_crtdds\_data.sas driver program located in the <cstSampleLibrary>\cdisc-crtdds-1.0-1.5\programs directory. This step is optional.

Create the define.xml file by submitting the create\_crtdds\_define.sas driver program. This driver program generates the define.xml file from the 39 CRT-DDS data sets that were created above. It also calls the crtdds\_xmlvalidate macro to validate the XML file structure.

Name	Date modified	Type	Size
create_crtdds_define.sas	8/28/2013 11:51 AM	SAS System Program	10 KB
create_crtdds_define_adam.sas	8/28/2013 11:51 AM	SAS System Program	10 KB
create_crtdds_define_pdf.sas	8/28/2013 11:51 AM	SAS System Program	10 KB
create_crtdds_define_pdf_adam.sas	8/28/2013 11:51 AM	SAS System Program	10 KB
create_crtdds_from_adam.sas	8/28/2013 11:51 AM	SAS System Program	11 KB
create_crtdds_from_sdtm.sas	8/28/2013 11:51 AM	SAS System Program	12 KB
create_sascrtdds_fromxml.sas	8/28/2013 11:51 AM	SAS System Program	13 KB
import_sascrtdds_fromxml_export_toxml.sas	8/28/2013 11:51 AM	SAS System Program	10 KB
validate_crtdds_data.sas	8/28/2013 11:51 AM	SAS System Program	12 KB
validate_crtdds_data_adam.sas	8/28/2013 11:51 AM	SAS System Program	12 KB

The define.xml file is written to the <cstSampleLibrary>\cdisc-crtdds-1.0-1.5\sourcexml directory.

Name	Date modified	Type	Size
define.pdf	8/28/2013 11:51 AM	Adobe Acrobat Doc...	761 KB
define.xml	8/28/2013 11:51 AM	XML File	1,390 KB

## Study Template