Paper PP06

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

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The SAS® Clinical Standards Toolkit provides support for registering the metadata associated with multiple CDISC standards, including SDTM, SEND, ADaM, CRT-DDS (reading and creating define.xml files), and ODM (reading and creating ODM xml files). Having this metadata registered, enables a large variety of processes defined in the SAS® Clinical Standards Toolkit to utilize this metadata. One of the processes is the creation of a CRT-DDS define.xml file, describing the metadata associated with a study (data sets, variables, controlled terms, derivations and value-level metadata). However, the SAS® Clinical Standards Toolkit can also import the metadata contained within a define.xml file. This means that the define.xml can be used as a metadata template for study set-up. This poster visualizes an example of a process where a define.xml file is used as a transfer vehicle for metadata as received from a 3rd party (CRO, partner, etc...). This metadata is then used as a template for study set-up and ultimately for creating a define.xml file describing the study. The poster shows how the SAS® Clinical Standards Toolkit provides the metadata and macros to make this process happen.

The following workflows assume a working knowledge of SAS® Clinical Standards Toolkit and therefore are a high level overview of the processes. It is assumed the user understands the base constructs such as initializing the product and modifying the sasreferences data set to point to appropriate input and output folders. For users unfamiliar with the product there is a list of references and resources at the conclusion of this paper.

Workflow 1- Going from a 3rd party define.xml to a study setup template

In this workflow the user receives a define.xml and wants to import the contents into the Clinical Standards Toolkit.

1. 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.

2. Source metadata that describes the SDTM domains and columns is derived using information contained in the CRT-DDS data sets derived in step 1. Submit the create_sourcemetadata.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_createsrcmetafromcrtdds 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.

3. SAS formats that support SDTM controlled terminology are derived using information contained in the CRT-DDS data sets that were derived in step 1. 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.

At this point code can be written to extract the data from the source metadata files to recreate the domains for the study. In Clinical Standards Toolkit and new macro will be available to handle the production of these domains.

Workflow 2 - Creating a new define.xml from the study template

1. 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.

2. 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.

3. Submit the create_crtdds_fromsdtm.sas driver program to access the crtdds_sdtmtodefine 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 sample study library directory/cdisc-crtdds-1.0–1.5/data directory.

4. Validate the CRT-DDS data sets by submitting the validate_crtdds_data.sas driver program. This step is optional.

5. 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 in step 3. It also calls the crtdds_xmlvalidate macro to validate the XML file structure. The define.xml file is written to the sample study library directory/cdisc-crtdds-1.0–1.5/sourcexml directory.

   At this point, a valid define.xml file has been created from the SAS representation of the CRT-DDS model.

References:

Round Trip Ticket – Using the Define.xml file to Send and Receive your Study Specifications - presented by Julie Maddox, SAS Institute Inc., Cary, NC, USA at Phuse 2013 in Brussels, Belgium. Paper CD03.

The following website can be accessed by all customers to get the most recent documentation and white papers.

http://support.sas.com/rnd/base/cdisc/cst/index.html

Toolkit Documentation

Product documentation
for all production releases of SAS Clinical Standards Toolkit is available for download.

Tutorial files (.zip)
for Clinical Standards Toolkit 1.2 and 1.3. Unzip this archive into your c:\ directory. This ZIP file contains both the SAS 9.2 and SAS 9.1.3 files. If you extract the entire ZIP archive, you should get a copy of the Quick Start document along with two directories of tutorial files, cstQuickStart (for SAS 9.2) and cstQuickStart9.1.3 (for SAS 9.1.3).

Papers

These papers introduce you to SAS Clinical Standards Toolkit and can help you understand how it functions.

Version 1.5

- Using the SAS Clinical Standards Toolkit 1.5 for define.xml Creation (.pdf) by Lex Jansen, SAS Institute Inc., Cary, NC (PharmaSUG 2013)
- Using the SAS Clinical Standards Toolkit 1.5 to import CDISC ODM files (.pdf) | and workshop materials (.zip) by Lex Jansen, SAS Institute Inc., Cary, NC (PharmaSUG 2013)
- SAS Clinical Standards Toolkit 1.5 - How Do I Know My Metadata is Right? (.pdf) | and the presentation (.pdf) by Gene Lightfoot, SAS Institute Inc., Cary, NC (PhUSE 2012)
- Simplifying SAS Clinical Standards Toolkit - Where's the Easy Button? (.pdf) | and the presentation (.pdf) by Gene Lightfoot, SAS Institute Inc., Cary, NC (PhUSE 2012)
- SAS Clinical Standards Toolkit: define.xml and Value Level Metadata (.pdf) | and the presentation (.pdf) by Lex Jansen, SAS Institute Inc., Cary, NC (PhUSE 2012)
- The Implementation of Nested Value Level Metadata in the SAS Representation of the CRT-DDS v1.0.0 Model in the SAS Clinical Standards Toolkit (.pdf) by Lex Jansen, SAS Institute Inc., Cary, NC (SAS Institute white paper 2012)

Version 1.4 and Earlier

- Using the SAS Clinical Standards Toolkit 1.4 for define.xml creation (.pdf) | and workshop materials (.zip) by Lex Jansen, SAS Institute Inc., Cary, NC (PharmaSUG 2012)
- How to Register a New Custom Standard within the Clinical Standards Toolkit (.pdf) by Gene Lightfoot, SAS Institute Inc., Cary, NC (SAS Institute white paper 2011)
- Using the SAS Clinical Standards Toolkit to Work with the CDISC ODM Model (.pdf) by Lex Jansen, SAS Institute Inc., Cary, NC (PhUSE 2011)
- Implementing ADaM Using SAS Clinical Standards Toolkit 1.4 (.pdf) by Gene Lightfoot, SAS Institute Inc., Cary, NC (PhUSE 2011)
- Implementing, Managing, and Validating a Clinical Standard Using SAS Clinical Standards Toolkit 1.3 (.pdf) by Gene Lightfoot, SAS Institute Inc., Cary, NC (PhUSE 2010)
- Define.xml - Tips and Techniques for Creating CRT-DDS (.pdf) by Julie Maddox, SAS Institute Inc., Cary, NC, and Mark Lambrecht, SAS Institute Inc., Tervuren, Belgium (PhUSE 2010)
- The SAS Clinical Standards Toolkit (.pdf) by Dave Smith, SAS Institute Inc., Cary, NC (PhUSE 2009)
- Introduction to SAS Clinical Standards Toolkit (.pdf) by Andreas Mangold and Nicole Wachter, HMS Analytical Software GmbH, Heidelberg, Germany (PhUSE 2010)

What's Next?

Periodically, preproduction functionality for the next release of SAS Clinical Standards Toolkit is made available here. Users are encouraged to download and use this functionality, and post feedback on the SAS and Clinical Trials community to help guide development. For SAS Clinical Standards Toolkit 1.6, the following preproduction updates are under consideration:

- Support for CDISC-SDTM 3.1.4 (including any available Therapeutic Area and Device domains)
- Provide support for WebDAV and Oracle library and file access
- Full implementation of CDISC Define-XML 2.0
- Create define.xml for CDISC-SEND 3.0

Check back with this site periodically for updates. Contact your SAS representative if any of these updates are of particular interest to you, or if you have other suggestions for product updates.

SAS Clinical Standards Toolkit 1.6 is expected to be released on SAS 9.4, with consideration being given to release on SAS 9.3 as well.