

## Simplifying SAS Clinical Standards Toolkit – Where’s the Easy Button?

Gene Lightfoot, SAS Inc, Cary, NC, USA

SAS Clinical Standards Toolkit® (Toolkit) is a product designed to work specifically with the CDISC SDTM, ADaM, ODM, CRT-DDS, and SEND models. Toolkit is provided at no additional charge to licensed SAS users, and provides the metadata underpinnings for SAS’ Clinical Data Integration product and standardized data structures for JMP Clinical. Many of you have heard the stories about or faced the realities of using Toolkit: difficult to install, an overwhelming 500-page User’s Guide, no class or video training options, and, of course, SAS macros out the wazoo! But yet, you are here, and, after all, we ARE SAS programmers, and we can do ANYTHING! There really is no easy button, but this poster attempts to address the more common questions we receive from technical support along with tips and guidance on simplifying use of the product.

SAS Clinical Standards Toolkit (CST) conceptually can be divided into four quadrants:

- 1) CST Framework – contains macros and metadata that manages all standards registered within the product. Macros provide functionality to register, unregister, manage, report, and validate Toolkit and standard metadata. Metadata files are generated and maintained to provide reporting information on any standard.
- 2) CST Reference Metadata – within each standard registered to CST additional metadata is collected and maintained. This reference metadata is considered the “Gold” standard and dictates how study metadata is created and validated. The main reference metadata files most users will access are `reference_tables`, `reference_columns`, and `validation_master`. For SDTM 3.1.2, `reference_tables` provides all of the “domain” metadata for the domains listed in the CDISC Implementation Guide, `reference_columns` lists all of the column metadata within each domain from the Implementation Guide. `Validation_master` provides all of the metadata for the validation checks as provided freely by various vendors in the industry. In addition to standard specific metadata, standard specific macros are stored here and are consumed by Toolkit as needed.
- 3) CST Study Metadata – For each study within a standard there is a specific set of study metadata, this metadata can be used across multiple studies or created for individual studies. For the most part, this metadata is a copy or subset of the standard level metadata. Files most likely to be encountered by users are `source_tables` (shares same structure as `reference_tables`), `source_columns` (shares same structure as `reference_columns`), and `validation_control` (shares same structure as `validation_master`).
- 4) Controlled terminology, dictionaries, SAS Formats – Where applicable, Toolkit ships with the most recent release of the National Cancer Institute’s Controlled Terminologies for each of the standards included in Toolkit. Any customer dictionaries (MedDRA), SAS formats, etc. can be accessed by Toolkit as long as proper access is provided.

Listed below are workflows showing general steps when performing such actions as adding a new standard, modifying a standard, and modifying or adding a new study. These workflows comprise some of the most asked questions we receive from customers of the product. Since Toolkit is developed using open source SAS macro code, it is an ideal product for the customer to modify and customize as needed.

**References:** The following website can be accessed by all customers to get the most recent documentation and white papers. This site contains additional and more detailed information for the work flows described below.

<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.

- [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)
- [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)

## Preproduction Updates

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 1.5, the following preproduction updates are under consideration:

- Updates to the CDISC-ADaM model, such as ADAE and ADTTE
- Ability to create a define.xml file based on CDISC-ADaM content
- Additional CDISC-SDTM domains (such as those in support of medical devices and therapeutic areas) and changes captured in the SDTM Amendment 1
- Ability to create a printable (PDF) version of the define.xml file
- Support of value-level metadata for CDISC-CRTDDS
- Support of additional CDISC standards such as CDASH, SEND and PRM.

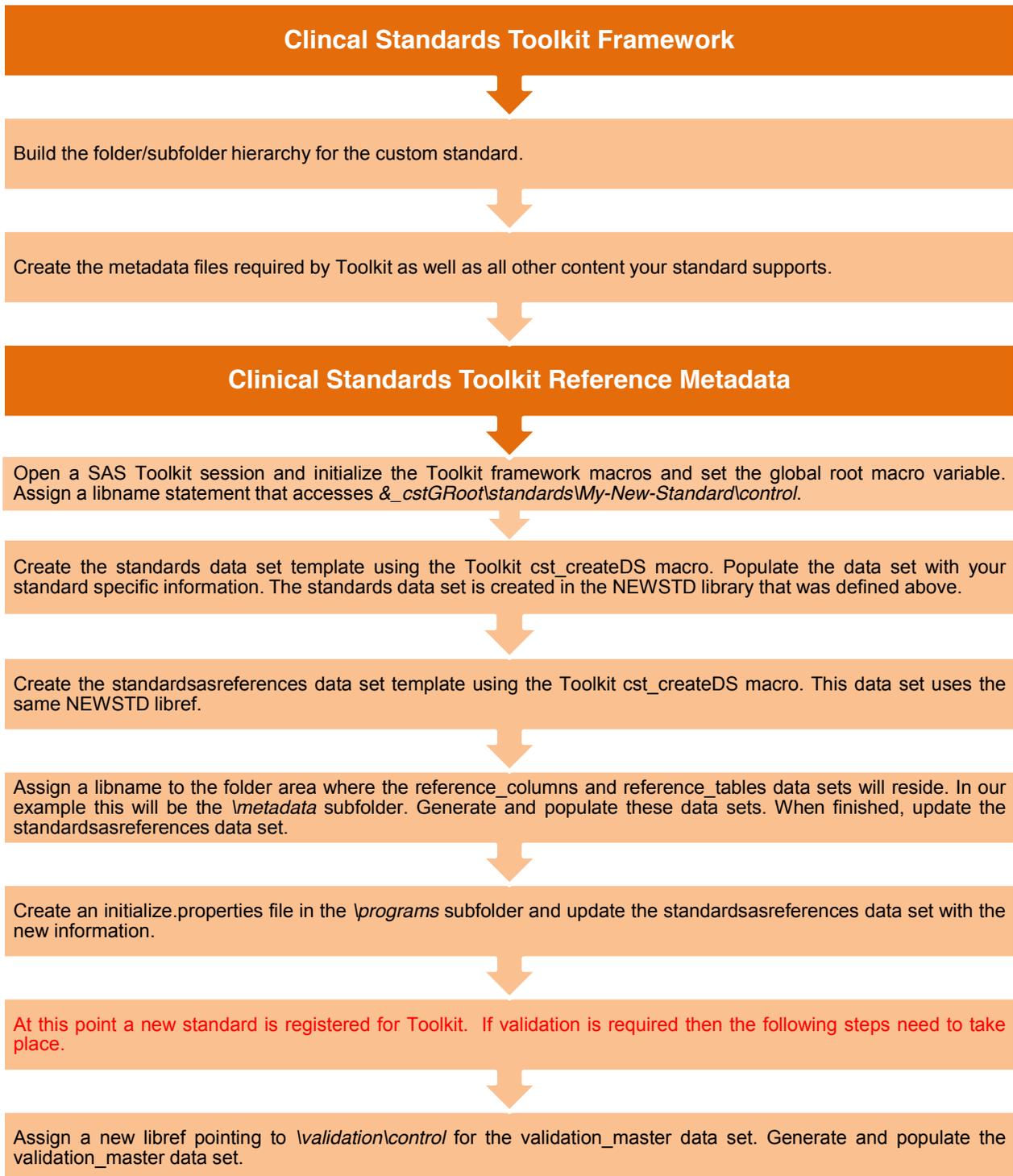
Check back with this site periodically for updates. Contact your SAS representative if any of these updates are of particular interest to you, or if you have other suggestions for product updates.

### Discussion Forum

To participate in a discussion about SAS and the clinical trials process, see the [SAS and Clinical Trials](#) community.

## Adding a New Standard

Toolkit 1.5 is shipped with the following standards: ADaM 2.1, CRT-DDS 1.0, ODM 1.3.0, ODM 1.3.1, SDTM 3.1.1, SDTM 3.1.2, SDTM 3.1.3, and SEND 3.0<sup>(1)</sup>. Customers can add a new standard by following the workflow listed below.



Create a validation.properties file in the *\programs* subfolder and copy any [Standard]\_validate.sas from Toolkit and place in the *\macros* folder.



Update the standardsreferences data set to include all of the additional information provided for the new standard to support validation.



Register the standard using the *cst\_registerStandard* framework macro. This macro sets the root path for this standard as *&\_cstGRoot\standards\My-New-Standard*.

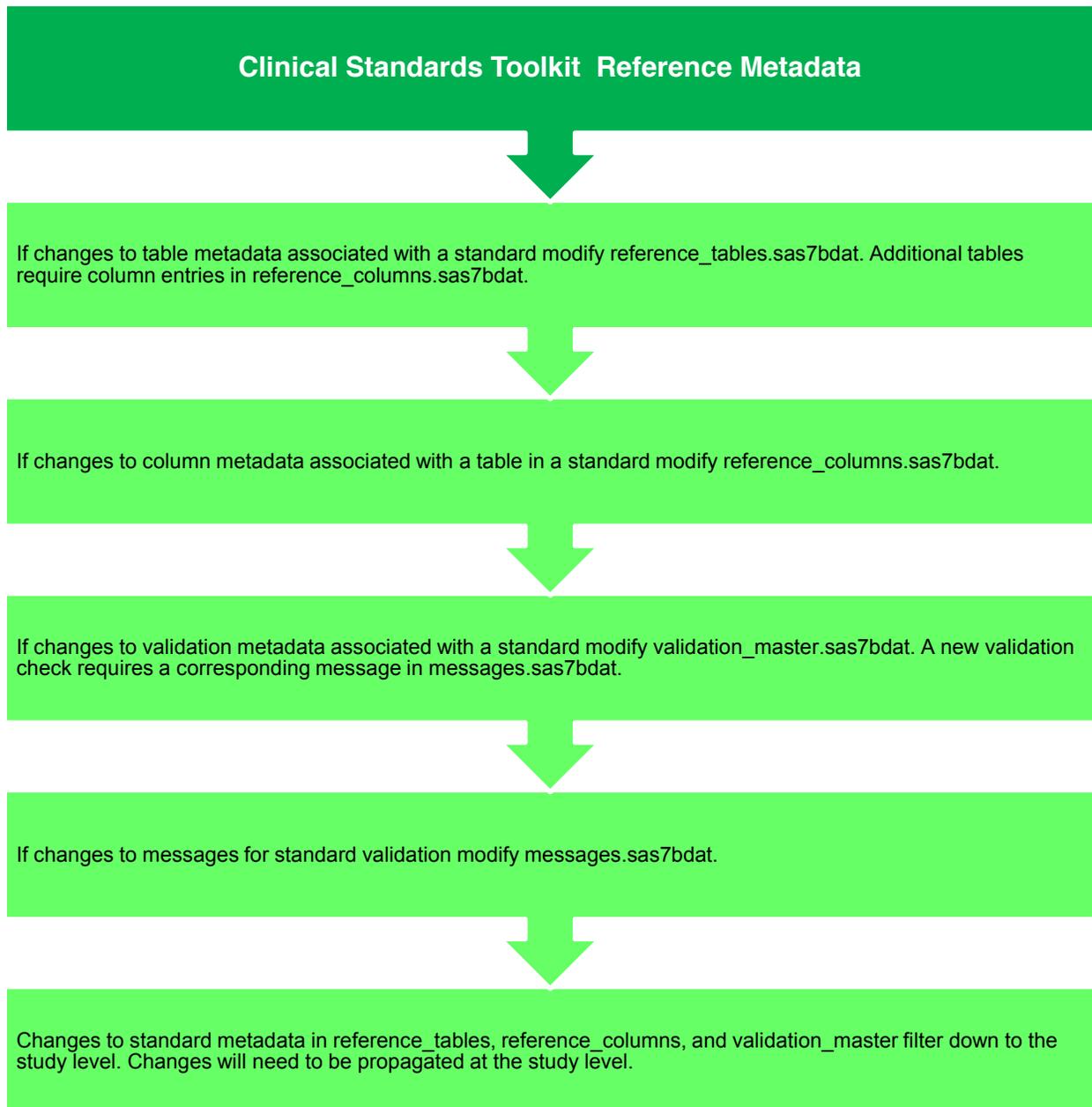


The next step is to add studies as needed. Please see section on adding a study.

- (1) This paper was written during development of Toolkit 1.5. The list of standards shipped with Toolkit 1.5 is subject to change.

## Customizing an existing Standard

For the most part, customizing an existing standard means changing or adding metadata to the standard. Any changes to standard metadata will most likely propagate down to the study level. When finished customizing a standard, be sure to validate any changes at the standard level have been propagated at the study level.



## Customizing/Adding a Study

Customizing or adding a study means changing or adding metadata, study files, and data sets. Changes here do not necessarily need to be updated at the standard level. For example, if a special column is needed for a single study it can be added here. Study metadata can be created for each study, if needed, or a single set of study metadata can be used across many studies.

