

Creating Define-XML version 2 including Analysis Results Metadata with the SAS® Clinical Standards Toolkit

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ABSTRACT

Analysis Results Metadata provide traceability for a given analysis result to the specific Analysis Dataset Model (ADaM) data that were used as input to generating the analysis result; they also provide information about the analysis method used and the reason the analysis was performed. Analysis Results Metadata will assist the reviewer by identifying the critical analyses, providing links between results, documentation, and datasets, and documenting the analyses performed.

This paper describes the Analysis Results Metadata extension 1.0 for Define-XML version 2, and also, how the SAS® Clinical Standards Toolkit 1.7.1 can be used to create Define-XML version 2.0 documents including Analysis Results Metadata.

This paper assumes that the reader is familiar with some basic XML concepts, and also with Define-XML version 2. An earlier paper by the author (see references [1]) contains both a short overview of the XML needed to understand this paper, and also an overview of the structure of a define.xml file based on Define-XML version 1.0.0. A detailed overview of differences between CRT-DDS version 1.0.0 and Define-XML version 2 can be found in "Define-XML v2 - What's New" [2].

Keywords: CDISC, Define-XML, define.xml, metadata, ADaM, Analysis Results Metadata, SAS Clinical Standards Toolkit

INTRODUCTION

In March 2013 the final version of the Define-XML 2.0.0 standard [3], formerly known as CRT-DDS (Case Report Tabulation Data Definition Specification) or "define.xml", as most people called it, was released by the CDISC XML Technologies team. Define-XML 2.0.0 is a major revision of the Define-XML standard for transmission of SDTM, SEND and ADaM metadata. Version 1.0.0 was released for implementation in February 2005 [4]. Define-XML has been a useful mechanism and critical component for providing Case Report Tabulations Data Definitions in an XML format for CDISC based electronic submissions to a regulatory authority such as the U.S. Food and Drug Administration (FDA). In August 2013 the FDA has also started accepting Define-XML version 2.0.0 [5]. In the latest version of Study Data Technical Conformance Guide (version3, March 2016) the FDA states that Define-XML version 2.0.0 is the preferred version of the Define-XML format [6].

In January 2015 CDISC published the Analysis Results Metadata (ARM) as an extension to the Define-XML 2.0.0 standard for the purpose of submissions to regulatory agencies such as the FDA as well as for the exchange of analysis datasets and key results between other parties.

Sponsors are now able to submit analysis results metadata as part of their submission to a regulatory agency like the FDA in the USA or the PMDA in Japan. Although the FDA has not yet referenced analysis results metadata as a required part of an electronic submission as of the writing of this paper (April 2016), they have mentioned in a presentation that there are sponsors who want to submit analysis results metadata as part of a submission [8].

The Japanese Pharmaceuticals and Medical Devices Agency (PMDA) have mentioned in their Technical Conformance Guide on Electronic Study Data Submissions (2015, [9]):

"In order for the review of clinical study data to progress smoothly, it is important that the relationship between the analysis results shown in the application documents and the analysis datasets is easily understandable. Therefore, the definition documents of the ADaM datasets should preferably include Analysis Results Metadata, which shows the relationship between the analysis results and the

corresponding analysis dataset and the variables used, for the analyses performed to obtain the main results of efficacy and safety and clinical study results that provide the rationales for setting of the dosage and administration".

The PMDA mentions further in the same document:

"For the format of the Analysis Results Metadata, the applicant should refer to the Analysis Results Metadata specification for Define-XML by CDISC to the extent possible, but if it is difficult to include it into the definition document, it is possible to submit it as a separated file in PDF format".

Even in the case that sponsors are required to submit analysis results metadata in an electronic submission, it adds significant value to a submission. A referenced paper by Dilorio and Abolafia (2015) gives good reasons why results level metadata can also provide value to sponsors and their agents [10].

BACKGROUND

When submitting clinical study data in electronic format to the FDA, or other regulatory agencies, not only information from trials has to be submitted, but also information to help understand the data. Part of this information is a data definition file, which is the metadata describing the format and content of the submitted electronic data sets. When submitting data in CDISC format it is required to submit the data definition file in the Define-XML specification format (define.xml) as prepared by the CDISC define.xml team.

A Define-XML file is a structured data definition specification in a machine-readable XML format that provides different kinds of metadata for:

- Datasets:
 - Name, domain, label, class, structure, purpose, keys, location, comments, documentation
- Variables:
 - Name, label, type, length, controlled terminology, origin, significant digit, display format, derivations, comments, documentation
- Variables under a condition:
 - Value level metadata or parameter value level metadata with the same kind of metadata as for 'regular' variables
- Controlled Terminology:
 - Standard or sponsor defined, name, type, valid values, decodes, reference to NCI code, external terminologies
- Derivations or Algorithms
- Comments
- Links to submission files:
 - Annotated CRF, Reviewers' Guide, source code files

The Analysis Results Metadata extension for Define-XML standard provides the metadata needed for traceability from a result used in a statistical display to the data in the analysis datasets:

- Identifiers and titles for the analysis displays (tables, figures) in the clinical study report
- Description of the specific analysis result within a display
- Purpose and reasons for performing the analysis
- The analysis parameter that is the focus of the analysis result
- Variables subject to analysis
- Datasets used to generate the analysis result
- Selection criteria for the records subject to analysis

- Corresponding description in the statistical analysis plan, analysis program name, and summary of the analytical methods
- Extract of the analysis program corresponding to the analysis method

The concept of results metadata for ADaM analyses and fields for representing this metadata were introduced in 2006 by CDISC with the publication of the Analysis Data Model (ADaM) Version 2.1 [11]. The document mentions that it is best practice to provide this metadata to assist the reviewer by identifying the critical analyses, providing links between results, documentation, and datasets, and documenting the analyses performed. Analysis results metadata are not needed or even advisable for every analysis included in a clinical study report or submission. The sponsor determines which analyses should have analysis results metadata.

The key components in ADaM Analysis Results Metadata are:

- Analysis Display metadata definitions
 - Analysis Result metadata definitions
 - Analysis parameter(s)
 - Analysis dataset(s)
 - Analysis variable(s)
 - Selection criteria
 - Documentation
 - Programming statements

The table below shows the table from the Analysis Data Model (ADaM) document with the metadata fields to be used to describe an analysis result. The word “Display” is used instead of “Table” as it is more generic, referring to tabular or graphical presentation of results.

Table 1 Analysis Results Metadata Fields (Analysis Data Model (ADaM) Version 2.1 document)

| Analysis Results Metadata Field | Description |
|--|--|
| DISPLAY IDENTIFIER | A unique identifier for the specific analysis display (such as a table or figure number) |
| DISPLAY NAME | Title of display, including additional information if needed to describe and identify the display (e.g., analysis population) |
| RESULT IDENTIFIER | Identifies the specific analysis result within a display. For example, if there are multiple p-values on a display and the analysis results metadata specifically refers to one of them, this field identifies the p-value of interest. When combined with the display identifier provides a unique identification of a specific analysis result. |
| PARAM | The analysis parameter in the BDS analysis dataset that is the focus of the analysis result. Does not apply if the result is not based on a BDS analysis dataset. |
| PARAMCD | Corresponds to PARAM in the BDS analysis dataset. Does not apply if the result is not based on a BDS analysis dataset. |
| ANALYSIS VARIABLE | The analysis variable being analyzed |
| REASON | The rationale for performing this analysis. It indicates when the analysis was planned (e.g., “Pre-specified in Protocol,” “Pre-specified in SAP,” “Data Driven,” “Requested by Regulatory Agency”) and the purpose of the analysis within the body of evidence (e.g., “Primary Efficacy,” “Key Secondary Efficacy,” “Safety”). The terminology used is sponsor defined. An example of a reason is “Primary Efficacy Analysis as Pre-specified in Protocol.” |

| Analysis Results Metadata Field | Description |
|---------------------------------|--|
| DATASET | The name of the dataset used to generate the analysis result. In most cases, this is a single dataset. However, if multiple datasets are used, they are all listed here. |
| SELECTION CRITERIA | Specific and sufficient selection criteria for analysis subset and / or numerator – a complete list of the variables and their values used to identify the records selected for the analysis. Though the syntax is not ADaM-specified, the expectation is that the information could easily be included in a WHERE clause or something equivalent to ensure selecting the exact set of records appropriate for an analysis. This information is required if the analysis does not include every record in the analysis dataset. |
| DOCUMENTATION | Textual description of the analysis performed. This information could be a text description, pseudo code, or a link to another document such as the protocol or statistical analysis plan, or a link to an analysis generation program (i.e., a statistical software program used to generate the analysis result). The contents of the documentation metadata element contains depends on the level of detail required to describe the analysis itself, whether or not the sponsor is providing a corresponding analysis generation program, and sponsor-specific requirements and standards. This documentation metadata element will remain free form, meaning it will not become subject to a rigid structure or controlled terminology. |
| PROGRAMMING STATEMENTS | The software programming code used to perform the specific analysis. This includes, for example, the model statement (using the specific variable names) and all technical specifications needed for reproducing the analysis (e.g., covariance structure). The name and version of the applicable software package should be specified either as part of this metadata element or in another document, such as a Reviewer's Guide (see Appendix B for more information about a Reviewer's Guide). |

It must be recognized that analysis results metadata fields in the Analysis Data Model (ADaM) Version 2.1 document are described in less technical terms and without implementation details.

Before there was an official specification for submitting analysis results metadata there were several CDISC Pilot Projects where the usefulness of the concept was demonstrated [12]. Since there was no formal specification for the submission vehicle of analysis results metadata, the pilots used their own informal specifications.

The Analysis Results Metadata extension to the Define-XML version 2 specification document ([13]) handles the technical implementation of what is described in Analysis Data Model (ADaM) Version 2.1 document.

Along with the Analysis Results Metadata v1.0 specification, the distribution package includes:

- The Analysis Results Metadata 1.0 XML schema
- An ADaM based Define-XML version 2.0 example and its HTML rendition
- A sample XSL stylesheet for the Define-XML example

THE FOUNDATION FOR THE ANALYSIS RESULTS METADATA EXTENSION

The Analysis Results Metadata for Define-XML standard is based on the CDISC Operational Data Model (ODM) XML schema [14]. The new Define-XML version 2 takes full advantage of the latest ODM version 1.3.2.

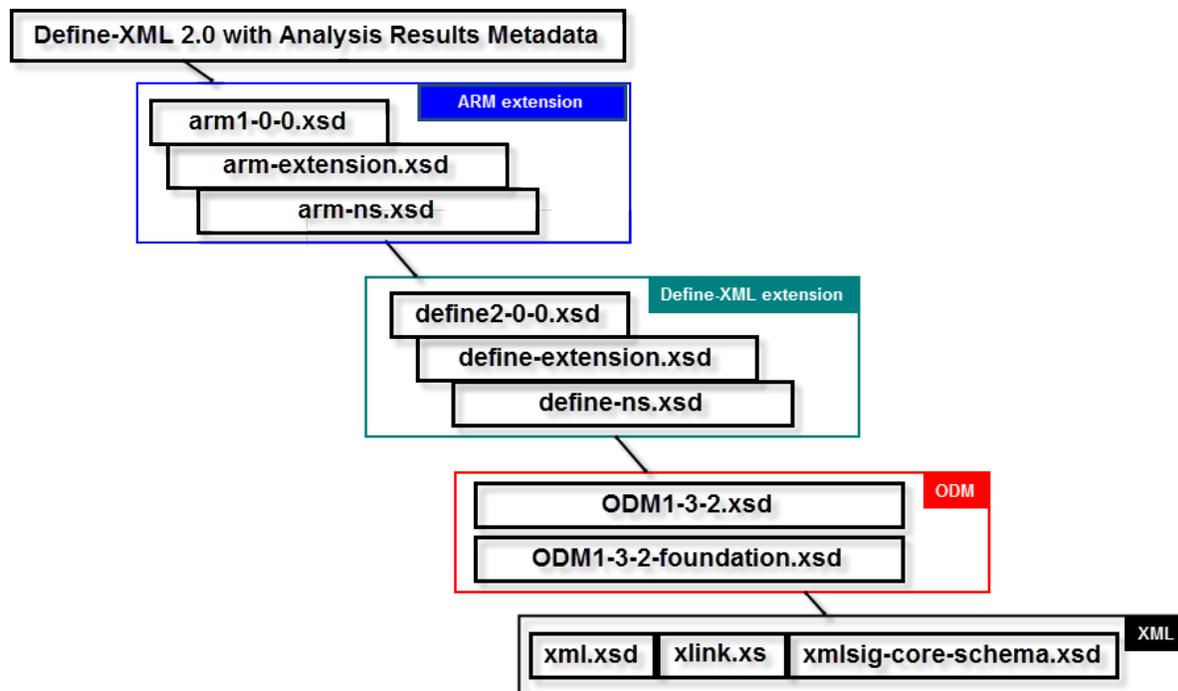
The CDISC Operational Data Model is a vendor neutral, platform independent XML format for interchange and archival of clinical study data. The model represents study metadata, administrative metadata, reference data and subject data associated with a clinical trial. The ODM format is defined by an XML schema and a specification.

One of the features of the ODM is a standardized mechanism for defining schema extensions to provide functionality needed to support interchange requirements for specialized use cases.

To address the specific needs of data transmission in support of regulatory submissions, CDISC has developed the

Define-XML model, which is implemented as an extension to the ODM foundation schema. These extensions follow the guidelines for Vendor Extensions provided in the ODM specification and comply with the W3C XML Schema 1.0 specification. The XML schema files for the Define-XML standard are available online [3]. Figure 1 depicts the extension mechanism.

Figure 1 Analysis Results Metadata 1.0 for Define-XML v2 as an ODM 1.3.2 extension



Although Define-XML version 1 has been a successful standard since 2005, there were good reasons to use Define-XML version 2.0 for the Analysis Results Metadata extension.

ARM uses several features that were new in the Define-XML version 2 standard:

- Explicit support for document references.
- Referencing short comments self-contained in the Define-XML document or long comments referenced in external documents
- The Where Clause mechanism is used for implementing selection criteria definitions that describe analysis data subsets

Figure 2 shows how the Analysis Results Metadata extension fits in a Define-XML version 2.0 document. Apart from the inclusion of the Analysis Results Metadata (`arm:AnalysisResultDisplays`) element, it is needed to add content to 3 more sections:

- Where Clause Definitions (`def:WhereClauseDef`)
- Comments (`def:CommentDef`)
- Referenced Documents (`def:leaf`)

Figure 2 Structure of Define-XML v2 with Analysis Results Metadata 1.0

```

<?xml version="1.0" encoding="UTF-8"?>
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3"
  xmlns:def="http://www.cdisc.org/ns/def/v2.0"
  xmlns:xlink="http://www.w3.org/1999/xlink"
  xmlns:arm="http://www.cdisc.org/ns/arm/v1.0"
  ODMVersion="1.3.2" FileType="Snapshot" FileOID="CDISC-Sample"
  CreationDateTime="2014-03-28T11:07:23:00"
  Originator="CDISC ADaM Metadata Team">
  <Study OID="cdisc01">
    <GlobalVariables>
      <StudyName>CDISC Sample</StudyName>
      <StudyDescription>CDISC-Sample Data Definitions</StudyDescription>
      <ProtocolName>CDISC-Sample</ProtocolName>
    </GlobalVariables>
    <MetaDataVersion OID="MDV.CDISC01.ADaMIG.1.0.ADaM.2.1"
      Name="Study CDISC-Sample, Data Definitions"
      Description="Study CDISC01, Data Definitions"
      def:DefineVersion="2.0.0"
      def:StandardName="ADaM-IG"
      def:StandardVersion="1.0">
      < Supplemental Data Definitions (def:SupplementalDoc) >
      < Value Level Metadata (def:ValueListDef) >
      < Where Clause Definitions (def:WhereClauseDef) >
      < Domain Level Metadata (ItemGroupDef) >
      < Variable Level Metadata (ItemDef) >
      < Controlled Terminology Metadata (CodeList) >
      < Computational Algorithms (MethodDef) >
      < Comments (def:CommentDef) >
      < Referenced Documents (def:leaf) >
      < Analysis Results Metadata (arm:AnalysisResultDisplays) >
    </MetaDataVersion>
  </Study>
</ODM>

```

SAS® CLINICAL STANDARDS TOOLKIT

The SAS Clinical Standards Toolkit focuses on standards defined by the Clinical Data Interchange Standards Consortium (CDISC). CDISC is a global, open, multidisciplinary, nonprofit organization that has established standards to support the acquisition, exchange, submission, and archival of clinical research data and metadata. The CDISC mission is to develop and support global, platform-independent data standards that enable information-system interoperability, which, in turn, improves medical research and related areas of health care. The SAS Clinical Standards Toolkit is not limited to supporting CDISC standards. The SAS Clinical Standards Toolkit framework is designed to support the specification and use of any user-defined standard.

SAS Clinical Standards Toolkit 1.6 and newer already had the capability to create a complete Define-XML version 2.0 document. With SAS Clinical Standards Toolkit 1.7.1 a Define-XML version 2.0 document can now also include the Analysis Results Metadata version 1.0 extension, as published by CDISC. An earlier paper by this author showed how to create a Define-XML version 2.0 document with the SAS Clinical Standards Toolkit 1.6 [15].

The SAS Clinical Standards Toolkit 1.7.1 (see reference [16]) includes support for the following CDISC standards:

- SDTM 1.3.1, 3.1.2, 3.1.3 and 3.2
- An initial implementation of the CDISC SEND 3.0 standard, including definition of all domains and columns.
- ADaM 2.1 (ADSL, Basic Data Structure, ADAE) and Analysis Results Metadata templates, as well as new validation checks in support of ADAE and ADTTE.
- CRT-DDS 1.0 (define.xml), including define.pdf and Value Level metadata support.
- Dataset-XML 1.0:
 - Creating Dataset-XML files from SAS data sets
 - Creating SAS data sets from Dataset-XML files
 - Validating Dataset-XML files against an XML schema
 - Comparing original SAS data sets with SAS data sets created from Dataset-XML files
- Define-XML 2.0:
 - A complete definition of the metadata model for CDISC Define-XML 2.0 (including Analysis Results Metadata)
 - Creation of a complete Define-XML 2.0 file based on study metadata, with study metadata examples from SDTM 3.2 and ADaM 2.1
 - Validation of a Define-XML 2.0 file against the XML schema definition, as published by CDISC
 - Import of a Define-XML 2.0 file into the SAS representation of the Define-XML 2.0 metadata model
 - support of creating an initial version of the SAS source metadata data sets (source_study, source_tables, source_columns, source_codelists, source_values, source_documents, and source_analysisresults) that serve as input for creating a Define-XML v2.0 file
- ODM 1.3.0 and ODM 1.3.1, including support for the extraction of ODM Clinical data and ODM Reference data into SAS data sets.
- The implementation of CT 1.0.0, a tool to support the import of NCI CDISC Controlled Terminology in the ODM XML format into SAS data sets and SAS format catalogs.
- CDISC Controlled Terminology packages that includes terminology sets as posted to the [NCI FTP](#) site.
- Furthermore, a set of macro tools to validate the SAS Clinical Standards Toolkit metadata itself (“Internal validation”).
- Metadata Management tools to add, update and delete Toolkit metadata

SAS Clinical Standards Toolkit 1.7.1 is supported with SAS 9.4 (TS1M2) or later on Windows x64 and Linux x64.

Each SAS Clinical Standards Toolkit standard provides a SAS representation of the published source guidelines or source specification. The SAS representation is designed to serve as a model or template of the source specification. Two key design requirements shaped the implementation of the SAS Clinical Standards Toolkit standards.

- 1) Each supported standard is represented in one or more SAS files. This facilitates these points:
 - It provides SAS users with an implementation of data models and standards that are based on SAS.
 - It enables you to use SAS routines to assess how well any user-defined set of data and metadata conforms to the standard.
 - It enables you to use SAS code to read and derive files in other formats (for example, XML).

Each SAS Clinical Standards Toolkit standard is an optimized reference standard from a SAS perspective.

- 2) You are able to define your own customized standards, or you are able to modify existing SAS standards.

Since a Define-XML file does not have a 2-dimensional data structure, it is not a trivial task to translate this hierarchical file to a number of SAS data set with rows and columns. SAS has defined a relational data model that represents a Define-XML file.

The highly structured nature of CDISC Define-XML data requires that any mapping to a relational format include a large number of data sets, with foreign key relationships to help preserve the intended non-relational object structure. In the SAS Clinical Standards Toolkit, foreign key relationships are enforced when validating the CDISC Define-XML data sets.

CREATING DEFINE-XML VERSION WITH THE SAS CLINICAL STANDARDS TOOLKIT

There are three key macros that are provided with the SAS Clinical Standards Toolkit that support creation of a CDISC Define-XML 2.0 define.xml file. The three macros are listed in the order in which they are executed:

1. The **define_sourcetodefine** macro creates the tables for the SAS representation of the Define-XML 2.0 files from study metadata. This macro, using SDTM or ADaM table and column metadata as its source, populates a subset of the Define-XML 2.0 data sets.
2. The **define_write** macro creates the define.xml file from the SAS representation of the CDISC Define-XML 2.0 files.
3. The **cstutilxmlvalidate** macro validates that the XML file is syntactically correct according the XML schema that is associated with the CDISC Define-XML 2.0 standard.

These macros are called by driver programs that are responsible for properly setting up each SAS Clinical Standards Toolkit process to perform a specific SAS Clinical Standards Toolkit task. Several sample driver programs are provided with the SAS Clinical Standards Toolkit CDISC Define-XML 2.0 standard related to the creation of the define.xml file.

Here is the purpose of each of these driver programs:

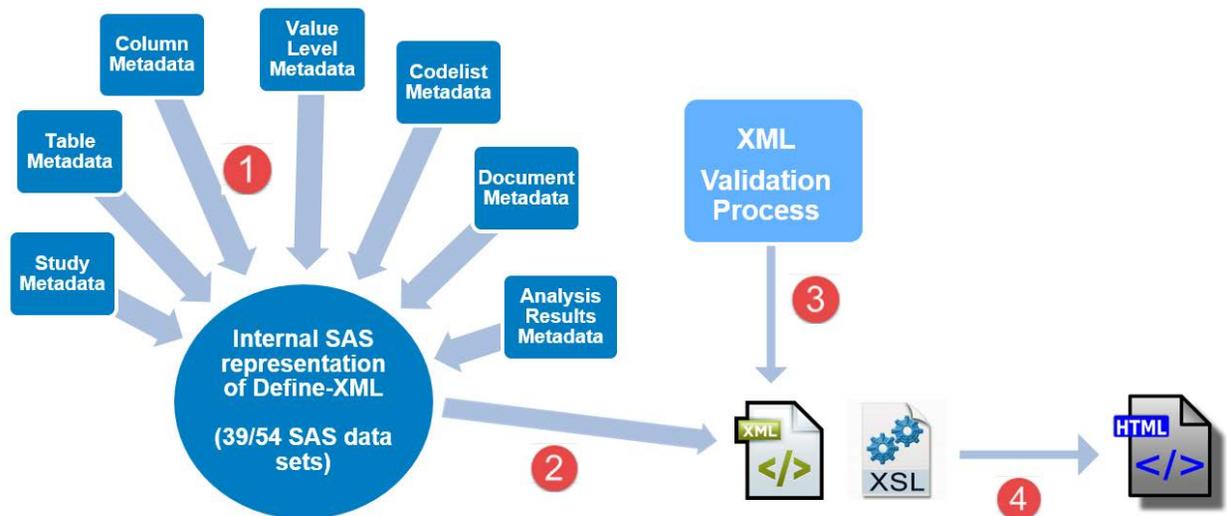
- The `create_sasdefine_from_source.sas` driver program sets up the required metadata and SASReferences data set for the sample study. It runs the `define_sourcetodefine` macro. It creates the SAS representation of the CDISC Define-XML 2.0 data sets from the sample study source metadata data sets.
- The `create_definexml.sas` driver program creates the CDISC Define-XML 2.0 define.xml file from the SAS representation of the CDISC Define-XML 2.0 data sets. It runs the `define_write` and `cstutilxmlvalidate` macros. This driver program creates and validates the XML syntax for the define.xml file.
- The `create_definexml_from_source_adam.sas` combines the previous two driver programs into one driver program.

These driver programs are examples that are provided with the SAS Clinical Standards Toolkit. You can use these driver programs or create your own. The names of these driver programs are not important. However, the content is important and demonstrates how the various SAS Clinical Standards Toolkit framework macros are used to generate the required metadata files.

Figure 3 shows the complete process for creating a complete Define-XML version 2 in the SAS Clinical Standards Toolkit. The following steps are identified:

1. Run the **define_sourcetodefine** macro to create the tables for the SAS representation of the Define-XML 2.0 files from study metadata.
2. Run the **define_write** macro to create the define.xml file from the SAS representation of the CDISC Define-XML 2.0 files.
3. Run the **cstutilxmlvalidate** macro to validate the define.xml file against the XML schema that is associated with the CDISC Define-XML 2.0 standard.
4. Run PROC XSL to create an HTML document from the define.xml file and the XSL stylesheet that comes with the SAS Clinical Standards Toolkit.

Figure 3 The SAS macro process to create a valid Define-XML 2.0 document



For Define-XML 2.0 the following source metadata SAS data sets are defined in SAS Clinical Standards Toolkit 1.7.1:

- source_study:
 - Metadata about the study, such as study name, study description and protocol name.
- source_tables:
 - Domain metadata, such as name, domain, description (label), class, structure, purpose, keys, data location, comments and documentation reference.
- source_columns
 - Column metadata, such as name, description (label), order number, datatype, length, codelist, origin, significant digits, display format, derivation (algorithm), comments and documentation reference.
- source_values
 - Value level metadata, where a condition is defined in the WHERECLAUSE column.
Example WHERECLAUSE values are:
 - (LBTESTCD EQ "BILI") AND (LBCAT EQ "CHEMISTRY") AND (LBSPEC EQ "BLOOD")
 - VSTESTCD EQ "HEIGHT"
 - PARAMCD IN ("ACITM01","ACITM02","ACITM03")
 - PARAMCD NOTIN ("ACTOT")
 - The column which the value level metadata is attached to, is defined by the TABLE and COLUMN columns. Apart from the WHERECLAUSE column, this data set contains the same kind of metadata as the source_columns data set.

- source_codelists:
 - Metadata related to Controlled Terminology, such as name, description, datatype, SAS formatname, valid values, decodes, rank, order number, reference to NCI code, external terminologies
- source_documents:
 - Metadata related to referenced documents, such as annotated CRF, reviewer guides or other supplemental documents. Records in this data set can be linked to source_tables, source_columns, source_values, or source_analysisresults data sets by the combination of the TABLE, COLUMN, WHERECLAUSE, DISPLAYIDENTIFIER and RESULTIDENTIFIER columns. Page numbers and named destinations in PDF files can be defined in this data set as well. Documents are attached to comments, methods or origins based on the value of the DOCTYPE column. Valid values of the DOCTYPE column in SAS Clinical Standards Toolkit 1.7 were: COMMENT, CRF or METHOD. Version 1.7.1 adds the following values: SUPPDOC, DISPLAY, RESULTDOC and RESULTCODE.
- Source_analysisresults:
 - Metadata related to analysis displays and results: display identifier, display name, display description, result identifier, result description, analysis purpose and reason, parameter column, analysis variables, analysis datasets, selection criteria (WhereClause), Selection criteria for the records subject to analysis, result programming code and context, result documentation.

The complete structure of the SAS source metadata data sets can be found in [Appendix 1](#).

The **define_sourcetodef** macro extracts data from the SDTM or ADaM metadata files. Depending on the available source information, the macro attempts to convert the information into the tables that represent the SAS interpretation of the CDISC Define-XML 2.0 model.

The parameters in table 2 must be set before submitting the **define_sourcetodef** macro.

Table 2 define_sourcetodef macro parameters

| Parameter | Required | Description |
|----------------------------------|----------|--|
| _cstOutLib | Yes | The library reference where the resulting tables are written. |
| _cstSourceTables | Yes | The data set that contains the metadata for the domains to include in the Define-XML file. |
| _cstSourceColumns | Yes | The data set that contains the metadata for the Domain columns to include in the Define-XML file. |
| _cstSourceCodeLists | No | The data set that contains the metadata for the CodeLists to include in the Define-XML file. |
| _cstSourceValues | No | The data set that contains the metadata for the Value Level columns to include in the Define-XML file. |
| _cstSourceDocuments | No | The data set that contains the metadata for document references to include in the Define-XML file. |
| _cstSourceAnalysisResults | No | The data set that contains the metadata for analysis results to include in the Define-XML file. |
| _cstFullModel | Yes | Create all data sets in the Define-XML model (Y) or only the core model (N). The default is N. |
| _cstLang | No | The ODM TranslatedText/@lang attribute. |
| _cstCheckLengths | Yes | Check the actual value lengths of character variables against the lengths defined in the metadata templates. |

Here is an example of a call to the define_sourcetodefne macro:

```
%define_sourcetodefne(
  _cstOutLib=srcdata,
  _cstSourceStudy=sampdata.source_study,
  _cstSourceTables=sampdata.source_tables,
  _cstSourceColumns=sampdata.source_columns,
  _cstSourceCodeLists=sampdata.source_codelists,
  _cstSourceDocuments=sampdata.source_documents,
  _cstSourceValues=sampdata.source_values,
  _cstSourceAnalysisResults=sampdata.source_analysisresults,
  _cstFullModel=N,
  _cstCheckLengths=Y,
  _cstLang=en
);
```

In the example, the define_sourcetodefne macro extracts data from the SDTM, SEND, or ADaM source metadata tables in the sampdata library and writes all of the tables that represent the SAS interpretation of the CDISC Define-XML 2.0 model to the SAS srcdata library.

A source study data set (source_study) can only have one record and is required by this macro. The variables in Table 3 are all required in this data set.

Table 3 Variables required in the Source Study Metadata Data Set (source_study)

| Variable | Description |
|------------------------------|--|
| SASRef | Libname reference. |
| StudyName | The name of the study. This value is used to populate the srcdata.study.studyname column. |
| StudyDescription | The description of the study. This value is used to populate the srcdata.study.studydescription column. Note: You cannot use commas, semicolons, or quotation marks in the description. |
| ProtocolName | The name of the protocol for the study. This value is used to populate the srcdata.study.protocolname column. |
| StudyVersion | The name of the define document to create. This value is used to populate the srcdata.metadataversion.oid column. |
| FormalStandardVersion | The formal version of the standard as used in Define-XML 2.0 This value is used to populate the srcdata.definedocument.standardversion column (For example, "1.0" for ADaM.) |
| FormalStandardName | The formal name of the standard as defined by the Define-XML 2.0 specification. This value is used to populate the srcdata.definedocument.standardname column (For example, ADaM-IG.) |
| Standard | The name of the standard as it is registered in the SAS Clinical Standards Toolkit. (For example, CDISC-ADAM.) |
| StandardVersion | The version of the standard as it is registered in the SAS Clinical Standards Toolkit. (For example, 2.1.) |

Only a single study can be referenced in the source data sets. The define_sourcetodomain macro will only select records from the source_tables, source_columns, source_codelists, source_values, source_documents, and source_analysisresults data sets whose STUDYVERSION column value is equal to the value of the STUDYVERSION column in the source_study data set. Figure 4 shows an example of the source_study data set.

Figure 4 Example of the source_study data set.

| VIEWTABLE: Sampdata.Source_study (Source Study Metadata) | | | | | |
|--|---------|--------------|------------------------------|--------------|---------------------------------|
| | sasref | studyname | studydescription | protocolname | studyversion |
| 1 | SRCDATA | CDISC-Sample | CDISC-Sample Data Definition | CDISC-Sample | MDV.CDISC01.ADaMIG.1.0.ADaM.2.1 |

| VIEWTABLE: Sampdata.Source_study (Source Study Metadata) | | | | |
|--|--------------------|-----------------------|------------|-----------------|
| | formalstandardname | formalstandardversion | standard | standardversion |
| 1 | ADaM-IG | 1.0 | CDISC-ADAM | 2.1 |

Figures 5 and 6 show examples of the source_tables and source_columns data sets. Not all columns are displayed in these examples.

Figure 5 Example of the source_tables data set (partial).

| VIEWTABLE: Sampdata.Source_tables (Source Table Metadata) | | | | | | | | | | | |
|---|----------|-------------------------|-------|--------|--------------------------------|--|--------------|---|----------|--|---|
| | table | label | order | domain | class | xmlpath | xmltitle | structure | purpose | keys | comment |
| 1 | ADAE | Adverse Events Analysis | 3 | | OCCURRENCE DATA STRUCTURE | ../transport/cdisc-adam-2.1/adae.xpt | adae.xpt | one record per subject per adverse event | Analysis | STUDYID USUBJID AETERM ASTDT AESEQ | See SAS program |
| 2 | ADQSADAS | ADAS-Cog Analysis | 2 | | BASIC DATA STRUCTURE | ../transport/cdisc-adam-2.1/adqsadas.xpt | adqsadas.xpt | One record per subject per parameter per analysis visit per analysis date | Analysis | STUDYID USUBJID PARAMCD AVISIT ADT | See referenced dataset creation program and Analysis Data Reviewer's Guide, Section 2.1 |
| 3 | ADSL | Subject Level Analysis | 1 | | SUBJECT LEVEL ANALYSIS DATASET | ../transport/cdisc-adam-2.1/adsl.xpt | adsl.xpt | one record per subject | Analysis | STUDYID USUBJID | Screen Failures are excluded since they are not needed for this study analysis. See Analysis Data Reviewer's Guide, page 6. |

Figure 6 Example of the source_columns data set (partial).

| VIEWTABLE: Sampdata.Source_columns (Source Column Metadata) | | | | | | | | | | | | |
|---|----------|----------|---------------------------------------|-------|--------|---------------|--------------|--------------|-------------|-------------------|--|-------------------------|
| | table | column | label | order | length | displayformat | xmldatastype | xmlicodelist | origin | origindescription | algorithm | comment |
| 56 | ADQSADAS | STUDYID | Study Identifier | 1 | 12 | | text | | Predecessor | ADSL.STUDYID | | |
| 57 | ADQSADAS | SITEID | Study Site Identifier | 2 | 3 | | text | | Predecessor | ADSL.SITEID | | |
| 58 | ADQSADAS | SITEGR1 | Pooled Site Group 1 | 3 | 3 | | text | | Predecessor | ADSL.SITEGR1 | | |
| 59 | ADQSADAS | USUBJID | Unique Subject Identifier | 4 | 11 | | text | | Predecessor | ADSL.USUBJID | | |
| 60 | ADQSADAS | TRTSDT | Date of First Exposure to Treatment | 5 | 8 | date9. | integer | | Predecessor | ADSL.TRTSDT | | |
| 61 | ADQSADAS | TRTEDT | Date of Last Exposure to Treatment | 6 | 8 | date9. | integer | | Predecessor | ADSL.TRTEDT | | |
| 62 | ADQSADAS | TRTP | Planned Treatment | 7 | 20 | | text | CL.ARM | Predecessor | ADSL.TRTP | | |
| 63 | ADQSADAS | TRTPN | Planned Treatment (N) | 8 | 8 | | integer | CL.ARMN | Predecessor | ADSL.TRTPN | | |
| 64 | ADQSADAS | AGE | Age | 9 | 8 | | integer | | Predecessor | ADSL.AGE | | |
| 65 | ADQSADAS | AGEGR1 | Pooled Age Group 1 | 10 | 5 | | text | CL.AGEGR1 | Predecessor | ADSL.AGEGR1 | | |
| 66 | ADQSADAS | AGEGR1N | Pooled Age Group 1 (N) | 11 | 8 | | integer | CL.AGEGR1N | Predecessor | ADSL.AGEGR1N | | |
| 67 | ADQSADAS | RACE | Race | 12 | 32 | | text | CL.RACE | Predecessor | ADSL.RACE | | |
| 68 | ADQSADAS | RACEN | Race (N) | 13 | 8 | | integer | CL.RACEN | Predecessor | ADSL.RACEN | | |
| 69 | ADQSADAS | SEX | Sex | 14 | 1 | | text | CL.SEX | Predecessor | ADSL.SEX | | |
| 70 | ADQSADAS | ITTFLL | Intent-To-Treat Population Flag | 15 | 1 | | text | CL.YN | Predecessor | ADSL.ITTFLL | | |
| 71 | ADQSADAS | EFFFL | Efficacy Population Flag | 16 | 1 | | text | CL.YN | Predecessor | ADSL.FASFL | | |
| 72 | ADQSADAS | COMP24FL | Completers of Week 24 Population Flag | 17 | 1 | | text | CL.YN | Predecessor | ADSL.COMP24FL | | |
| 73 | ADQSADAS | AVISIT | Analysis Visit | 18 | 16 | | text | CL.AVISIT | Derived | | Derived based on windowing algorithm described in SAP, Section 8.2 | |
| 74 | ADQSADAS | AVISITN | Analysis Visit (N) | 19 | 8 | | integer | CL.AVISITN | Assigned | | | Numeric code for AVISIT |

The example of the source_values data set in Figure 7, used to define Parameter Value Level Metadata, shows that this data set looks very much like the source_columns data set. It has an extra column to describe the condition (WHERECLAUSE) for which the metadata is defined. The TABLE and COLUMN variables tell which variable the value list is attached to.

Figure 7 Example of the source_values data set (partial).

| VIEWTABLE: Sampdata.Source_values (Source Value Metadata) | | | | | | | | | | | |
|---|----------|--------|---|-----------------|--------|-------------|-------------|-------------|-------------------|---|--|
| | table | column | whereclause | label | length | xmldatatype | xmlcodelist | origin | origindescription | algorithm | comment |
| 1 | ADQSADAS | AVAL | PARAMCD IN ("ACITM14", "ACITM10", "ACITM12", "ACITM04", "ACITM03", "ACITM02", "ACITM07", "ACITM08", "ACITM09", "ACITM05", "ACITM06", "ACITM11", "ACITM01", "ACITM13") | Analysis Value | 8 | integer | | Derived | | QS.QSSTRESN where QSTESTCD=PARAMCD | |
| 2 | ADQSADAS | AVAL | PARAMCD EQ "ACTOT" | Analysis Value | 8 | integer | | Derived | | Sum of ADAS scores for items 1, 2, 4, 5, 6, 7, 8, 11, 12, 13, and 14, see Analysis Data Reviewers Guide (Page 3) for details on adjusting for missing values. | |
| 3 | ADQSADAS | DTYPE | PARAMCD NE "ACTOT" | Derivation Type | 7 | text | CL.DTYPE | Assigned | | | Value: null |
| 4 | ADQSADAS | DTYPE | PARAMCD EQ "ACTOT" | Derivation Type | 7 | text | CL.DTYPE | Assigned | | | Value: LOCF denotes that the LOCF imputation method was used to impute the value for the given parameter and analysis visit. |
| 5 | ADQSADAS | QSSEQ | PARAMCD NE "ACTOT" | Sequence Number | 8 | integer | | Predecessor | QS.QSSEQ | | |
| 6 | ADQSADAS | QSSEQ | PARAMCD EQ "ACTOT" | Sequence Number | 8 | integer | | Assigned | | | Set QSSEQ to missing for post baseline records. Set to QS.QSSEQ where QS.VISIT=BASELINE and QS.QSTESTCD=ACTOT. |

Figure 8 shows an example of Controlled Terminology metadata. The source_codelists table is linked to the source_columns table and the source_values table through the SASFORMATNAME column:

source_codelists.CODELIST = source_columns.XMLCODELIST
source_codelists.CODELIST = source_values.XMLCODELIST

Figure 8 Example of the source_codelists data set (partial).

| VIEWTABLE: Sampdata.Source_codelists (Source Codelist Metadata) | | | | | | | | | | | | | |
|---|------------|---|----------------|------------------|---------------|----------------------|---------------|------------|-----------------|------|-------------|------------|---------|
| | codelist | codelistname | codelistnicode | codelistdatatype | sasformatname | codedvaluechar | codedvaluenum | decodetext | codedvaluencode | rank | ordernumber | dictionary | version |
| 1 | CL.AECAUS | Causality | | text | | NONE | . | | | 1 | . | | |
| 2 | CL.AECAUS | Causality | | text | | POSSIBLE | . | | | 2 | . | | |
| 3 | CL.AECAUS | Causality | | text | | PROBABLE | . | | | 3 | . | | |
| 4 | CL.AECAUS | Causality | | text | | REMOTE | . | | | 4 | . | | |
| 5 | CL.AEDICT | Adverse Event Dictionary | | text | | | . | | | . | . | MedDRA | 8.0 |
| 6 | CL.AESEV | Severity/Intensity Scale for Adverse Events | C66769 | text | \$AESEV | MILD | . | Grade 1 | C41338 | 1 | . | | |
| 7 | CL.AESEV | Severity/Intensity Scale for Adverse Events | C66769 | text | \$AESEV | MODERATE | . | Grade 2 | C41339 | 2 | . | | |
| 8 | CL.AESEV | Severity/Intensity Scale for Adverse Events | C66769 | text | \$AESEV | SEVERE | . | Grade 3 | C41340 | 3 | . | | |
| 9 | CL.AGEGR1 | Age Group | | text | | <65 | . | | | 1 | . | | |
| 10 | CL.AGEGR1 | Age Group | | text | | 65-80 | . | | | 2 | . | | |
| 11 | CL.AGEGR1 | Age Group | | text | | >80 | . | | | 3 | . | | |
| 12 | CL.AGEGR1N | Age Group (N) | | integer | AGEGR1N | | 1 | <65 | | . | . | | 1 |
| 13 | CL.AGEGR1N | Age Group (N) | | integer | AGEGR1N | | 2 | 65-80 | | . | . | | 2 |
| 14 | CL.AGEGR1N | Age Group (N) | | integer | AGEGR1N | | 3 | >80 | | . | . | | 3 |
| 15 | CL.AGEU | Age Unit | C66781 | text | | YEARS | . | | C29848 | . | . | | |
| 16 | CL.ARM | Actual Treatment | | text | | Placebo | . | | | . | . | | 1 |
| 17 | CL.ARM | Actual Treatment | | text | | Xanomeline Low Dose | . | | | . | . | | 2 |
| 18 | CL.ARM | Actual Treatment | | text | | Xanomeline High Dose | . | | | . | . | | 3 |

Figure 9 shows an example of the source_documents data set. This data set defines metadata for references to supporting documents like the annotated Case Report Form (SDTM), and other types of supporting documents, like the Statistical Analysis Plan, the Clinical Study Report, or the Analysis Data Reviewer's Guide [18]. This data set can also have metadata for references to files with SAS programming code.

Figure 9 Example of the source_documents data set (partial)

| VIEWTABLE: Sampdata.Source_documents (Source Document Metadata) | | | | | | | | | | |
|---|------------|---|--------------------------------|------------------|-------------|----------|--------|--------------------|-------------------|----------------------|
| | doctype | href | title | pdfpagereftype | pdfpagerefs | table | column | whereclause | displayidentifier | resultidentifier |
| 1 | COMMENT | ../suppdocs/adae-sas.txt | adae.sas | | | ADAE | | | | |
| 2 | COMMENT | ../suppdocs/adqsadas-sas.txt | adqsadas.sas | | | ADQSADAS | | | | |
| 3 | COMMENT | ../suppdocs/analysis-data-reviewers-guide.pdf | Analysis Data Reviewer's Guide | NamedDestination | Section2.1 | ADQSADAS | | | | |
| 4 | COMMENT | ../suppdocs/analysis-data-reviewers-guide.pdf | Analysis Data Reviewer's Guide | PhysicalRef | 6 | ADSL | | | | |
| 5 | DISPLAY | ../suppdocs/dummy-csr.pdf | Table 14-3.01 | PhysicalRef | 2 | | | | RD.Table_14-3.01 | |
| 6 | DISPLAY | ../suppdocs/dummy-csr.pdf | Table 14-5.02 | PhysicalRef | 3 | | | | RD.Table_14-5.02 | |
| 7 | METHOD | ../suppdocs/analysis-data-reviewers-guide.pdf | Analysis Data Reviewer's Guide | PhysicalRef | 3 | ADQSADAS | AVAL | PARAMCD EQ "ACTOT" | | |
| 8 | RESULTCODE | ../suppdocs/at14-5-02-sas.txt | at14-5-02.sas | | | | | | RD.Table_14-5.02 | AR.Table_14-5.02.R.1 |
| 9 | RESULTDOC | ../suppdocs/dummy-sap.pdf | Statistical Analysis Plan | PhysicalRef | 4 | | | | RD.Table_14-3.01 | AR.Table_14-3.01.R.2 |
| 10 | RESULTDOC | ../suppdocs/dummy-sap.pdf | Statistical Analysis Plan | PhysicalRef | 5 | | | | RD.Table_14-5.02 | AR.Table_14-5.02.R.1 |
| 11 | RESULTDOC | ../suppdocs/dummy-sap.pdf | Statistical Analysis Plan | PhysicalRef | 4 | | | | RD.Table_14-3.01 | AR.Table_14-3.01.R.1 |
| 12 | SUPPDOC | ../suppdocs/analysis-data-reviewers-guide.pdf | Analysis Data Reviewer's Guide | | | | | | | |
| 13 | SUPPDOC | ../suppdocs/dummy-csr.pdf | Clinical Study Report | | | | | | | |
| 14 | SUPPDOC | ../suppdocs/dummy-sap.pdf | Statistical Analysis Plan | | | | | | | |

An explanation of the metadata in Figure 9 follows below.

- Record 1-2 References to SAS programs attached to a comment in tables ADAE and ADQSADAS
- Record 3 A reference to the Analysis Data Reviewer's Guide (analysis-data-reviewers-guide.pdf) attached to a comment in the ADQSADAS table with a PDF NamedDestination specified ("Section2.1"). This NamedDestination has to be defined in the PDF document.
- Record 4 A reference to page 6 in the Analysis Data Reviewer's Guide (analysis-data-reviewers-guide.pdf) attached to a comment in the ADQSADAS table.
- Records 5-6 Table references from analysis displays to physical pages in the Clinical Study Report. The value the DOCTYPE column ("DISPLAY") tells that these references are attached to the display as a whole.
- Record 7 A reference to page 3 in the Analysis Data Reviewer's Guide (analysis-data-reviewers-guide.pdf) to further explain a derivation (method) attached to an item defined by a WHERECLAUSE (Value Level Metadata), ADQSADA.AVAL where PARAMCD equals "ACTOT".
- Record 8 A reference from an analysis result within a display to a file with programming statements (at14-5-02.sas). The analysis result is identified by the DISPLAYIDENTIFIER and RESULTIDENTIFIER columns. The value the DOCTYPE column ("RESULTCODE") tells that these references are results documentation.
- Records 9-11 A reference from an analysis result within a display to a physical page within the Statistical Analysis Plan (at14-5-02.sas). The analysis result is identified by the DISPLAYIDENTIFIER and RESULTIDENTIFIER columns. The value the DOCTYPE column ("RESULTDOC") tells that these references are results documentation.
- Records 12-14 References to various documents: Analysis Data Reviewer's Guide, Clinical Study Report and Statistical Analysis Plan. No physical page numbers or named destination is defined. The value the DOCTYPE column ("SUPPDOC") tells that these references are not attached to a specific table, column, value level metadata item, display, or result. These references will be included in the def:SupplementalDoc element in the Define-XML document. A stylesheet typically will display links to these documents in the bookmarks section of the HTML rendition of the Define-XML document, as can be seen in Figure 10.

Figure 10 Example of a rendition of a Define-XML document that shows document references

ADaM-IG 1.0

- Analysis Data Reviewer's Guide
- Clinical Study Report
- Statistical Analysis Plan
- ▶ Analysis Results Metadata
- ▼ Analysis Datasets
 - ADSL (Subject Level Analysis)
 - ADQSADAS (ADAS-Cog Analysis)
 - ADAE (Adverse Events Analysis)
- ▶ Parameter Value Level Metadata
- ▶ Controlled Terminology
- ▶ Analysis Derivations
- ▶ Comments

| | |
|-----------------------------|--|
| Standard | ADaM-IG 1.0 |
| Study Name | CDISC-Sample |
| Study Description | CDISC-Sample Data Definition |
| Protocol Name | CDISC-Sample |
| Metadata Name | Data Definitions for CDISC-Sample, ADaM-IG 1.0 |
| Metadata Description | Data Definitions for CDISC-Sample, ADaM-IG 1.0 |

Analysis Results Metadata (Summary) for Study CDISC-Sample

| |
|---|
| <p>Table 14-3.01 Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)</p> <p>Dose response analysis for ADAS-Cog changes from baseline</p> <p>Pairwise comparisons to placebo for ADAS-Cog changes from baseline</p> <p>Table 14-5.02 Incidence of Treatment Emergent Serious Adverse Events by Treatment Group</p> <p>Incidence of Treatment Emergent Serious Adverse Events by Treatment Group</p> |
|---|

Figure 11 shows an example of the source_analysis data set. This data set contains metadata to support the Analysis Results Metadata extension to Define-XML version 2.0. The data set contains one record per analysis display per analysis result per analysis dataset.

The CODE column in the source_analysisresults data set contains programming statements. Any whitespace (blanks) or carriage returns ('OD'x) in in this column will be left unchanged by the SAS Clinical Standards Toolkit when creating the Define-XML file. An XSL stylesheet can then render this information in a formatted way when creating HTML. The SAS Clinical Standards Toolkit will convert "\n" to carriage returns ('OD'x) when creating the Define-XML file.

The stylesheet that comes with the Define-XML will display CODECONTEXT="SAS version 9.2" and CODE="proc glm data = ADQSADAS;\n where EFFF'L='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT";\n class SITEGR1;\n model CHG = TRTPN SITEGR1;\nrnrun;" as follows:

| | |
|------------------------|---|
| Programming Statements | <pre>[SAS version 9.2] proc glm data = ADQSADAS; where EFFF'L='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT"; class SITEGR1; model CHG = TRTPN SITEGR1; run;</pre> |
|------------------------|---|

Figure 11 Example of the source_analysisresults data set (partial)

| VIEWTABLE: Sampdata.Source_analysisresults (Source Analysis Results Metadata) | | | | | | | | |
|---|-------------------|---------------|---|----------------------|-----------------|------------------|-------------------------|---|
| | DisplayIdentifier | DisplayName | DisplayDescription | ResultIdentifier | ParameterColumn | AnalysisReason | AnalysisPurpose | ResultDescription |
| 1 | RD.Table_14-3.01 | Table 14-3.01 | Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population) | AR.Table_14-3.01.R.1 | PARAMCD | SPECIFIED IN SAP | PRIMARY OUTCOME MEASURE | Dose response analysis for ADAS-Cog changes from baseline |
| 2 | RD.Table_14-3.01 | Table 14-3.01 | Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population) | AR.Table_14-3.01.R.2 | PARAMCD | SPECIFIED IN SAP | PRIMARY OUTCOME MEASURE | Pairwise comparisons to placebo for ADAS-Cog changes from baseline |
| 3 | RD.Table_14-5.02 | Table 14-5.02 | Incidence of Treatment Emergent Serious Adverse Events by Treatment Group | AR.Table_14-5.02.R.1 | | SPECIFIED IN SAP | PRIMARY OUTCOME MEASURE | Incidence of Treatment Emergent Serious Adverse Events by Treatment Group |
| 4 | RD.Table_14-5.02 | Table 14-5.02 | Incidence of Treatment Emergent Serious Adverse Events by Treatment Group | AR.Table_14-5.02.R.1 | | SPECIFIED IN SAP | PRIMARY OUTCOME MEASURE | Incidence of Treatment Emergent Serious Adverse Events by Treatment Group |

| VIEWTABLE: Sampdata.Source_analysisresults (Source Analysis Results Metadata) | | | | | | | |
|---|--|--|-----------------|---|----------|---------------------|--|
| | TableJoinComment | ResultDocumentation | CodeContext | Code | Table | AnalysisVariables | WhereClause |
| 1 | | Linear model analysis of CHG for dose response; using randomized dose (0 for placebo; 54 for low dose; 81 for high dose) and site group in model. Used PROC GLM in SAS to produce p-value (from Type III SS for treatment dose). See page 4 (section 10.1.1) in the Statistical Analysis Plan. | SAS version 9.2 | proc glm data = ADQSADAS;\n where EFFFL="Y" and ANL01FL="Y" and AVISIT="Week 24" and PARAMCD="ACTOT";\n class SITEGR1;\n model CHG = TRTPN SITEGR1;\nrun; | ADQSADAS | CHG | (PARAMCD EQ "ACTOT") AND (AVISIT EQ "Week 24") AND (EFFFL EQ "Y") AND (ANL01FL EQ "Y") |
| 2 | | ANCOVA analysis of CHG performed to provide pairwise comparisons among treatment groups and adjusted means; using randomized treatment as class variable and site group as class variable in model and the baseline value as a covariate. See page 4 (section 10.1.1) in the Statistical Analysis Plan. | SAS version 9.2 | proc glm data = ADQSADAS;\n where EFFFL="Y" and ANL01FL="Y" and AVISIT="Week 24" and PARAMCD="ACTOT";\n class TRTPN SITEGR1;\n model CHG = TRTPN SITEGR1 BASE;\n means TRTPN / OM STDERR PDIF CL;\nrun; | ADQSADAS | CHG | (PARAMCD EQ "ACTOT") AND (AVISIT EQ "Week 24") AND (EFFFL EQ "Y") AND (ANL01FL EQ "Y") |
| 3 | Get denominators for percentages from ADSL and counts and numerators from ADAE. Join ADAE with ADSL based on the unique subject identifier (USUBJID) keeping only records in ADAE for the numerator. | Unique count of subjects that experienced an Adverse Event by Preferred Term, System Organ Class, and Treatment Group and percentages based on the number of subjects in the safety population within each treatment group. The total number of times an event occurred was recorded by Preferred Term, System Organ Class, and Treatment Group. Fisher's exact test was used for treatment comparison of event rates. See page 5 (section 11.2) in the Statistical Analysis Plan. | SAS version 9.2 | | ADAE | AEBODSYS AEDECOD | (TRTEML EQ "Y") AND (AESER EQ "Y") |
| 4 | Get denominators for percentages from ADSL and counts and numerators from ADAE. Join ADAE with ADSL based on the unique subject identifier (USUBJID) keeping only records in ADAE for the numerator. | Unique count of subjects that experienced an Adverse Event by Preferred Term, System Organ Class, and Treatment Group and percentages based on the number of subjects in the safety population within each treatment group. The total number of times an event occurred was recorded by Preferred Term, System Organ Class, and Treatment Group. Fisher's exact test was used for treatment comparison of event rates. See page 5 (section 11.2) in the Statistical Analysis Plan. | SAS version 9.2 | | ADSL | | SAFFL EQ "Y" |

For analysis results based on a Basic Data Structure (BDS) the PARAMETERCOLUMN contains the name of the variable that contains the short name of the analysis parameter (PARAM). It is expected that the PARAM variable is also part of the WHERECLAUSE that specifies the selection criteria for the analysis subset. The WHERECLAUSE contains a complete list of the variables and their values used to identify the records selected for the analysis.

[Appendix 2](#) contains the structure of the syntax of the WHERECLAUSE column as implemented by the SAS Clinical Standards Toolkit in a railroad diagram.

The following code can be used to create a Define-XML 2.0 file with the source metadata data sets as input:

```

%let _cstStandard=CDISC-DEFINE-XML;
%let _cstStandardVersion=2.0.0;

%cst_setStandardProperties(_cstStandard=CST-FRAMEWORK,_cstSubType=initialize);

%let studyRootPath=C:/cstSampleLibrary/cdisc-definexml-2.0.0-1.7;
%let studyOutputPath=C:/cstSampleLibrary/cdisc-definexml-2.0.0-1.7;
%let workPath=%sysfunc(pathname(work));
%let _cstSetupSrc=SASREFERENCES;

%cst_createdsfromtemplate(
  _cstStandard=CST-FRAMEWORK, _cstType=control,
  _cstSubType=reference, _cstOutputDS=work.sasreferences
);

proc sql;
  insert into work.SASReferences
  values ("CST-FRAMEWORK" "1.2" "messages"
    " " "messages" "libref" "input"
    "dataset" "N" " " " 1 " " ")
  values ("&_cstStandard" "&_cstStandardVersion" "messages"
    " " "defmsg" "libref" "input"
    "dataset" "N" " " " 2 " " ")
  values ("&_cstStandard" "&_cstStandardVersion" "autocall"
    " " "autol" "fileref" "input"
    "folder" "N" " " " 1 " " ")
  values ("&_cstStandard" "&_cstStandardVersion" "properties"
    "initialize" "inprop" "fileref" "input"
    "file" "N" " " " 1 " " ")
  values ("&_cstStandard" "&_cstStandardVersion" "results"
    "results" "results" "libref" "output"
    "dataset" "Y" " " "&studyOutputPath/results" .
    "definexml_results_adam.sas7bdat" " ")
  values ("&_cstStandard" "&_cstStandardVersion" "sourcemetadata"
    " " "sampdata" "libref" "input"
    "dataset" "N" " " "&studyRootPath/sascstdemodata/cdisc-adam-2.1/metadata" .
    "source_study.sas7bdat" " ")
  values ("&_cstStandard" "&_cstStandardVersion" "sourcedata"
    " " "srcdata" "libref" "input"
    "folder" "N" " " "%sysfunc(pathname(work))" . " " ")
  values ("&_cstStandard" "&_cstStandardVersion" "externalxml"
    "xml" "extxml" "fileref" "output"
    "file" "Y" " " "&studyOutputPath/sourcexml" .
    "define-adam-2.1.xml" " ")
  values ("&_cstStandard" "&_cstStandardVersion" "report"
    "outputfile" "html" "fileref" "output"
    "file" "Y" " " "&studyOutputPath/sourcexml" .
    "define-adam-2.1.html" " ")
  values ("&_cstStandard" "&_cstStandardVersion" "referencexml"
    "stylesheet" "xslt" "fileref" "output" "file" "Y" " " " " .
    "define2-0-0.xsl" " ")
  ;
quit;

*****;
* Process SASReferences file. *;
*****;
%cstutil_processsetup();

*****;
* Read the source metadata ;
*****;
%define_sourcetodefine(
  _cstOutLib=srcdata,
  _cstSourceStudy=sampdata.source_study,
  _cstSourceTables=sampdata.source_tables,
  _cstSourceColumns=sampdata.source_columns,
  _cstSourceCodeLists=sampdata.source_codelists,
  _cstSourceDocuments=sampdata.source_documents,
  _cstSourceValues=sampdata.source_values,
  _cstSourceAnalysisResults=sampdata.source_analysisresults
);

```

```

* Create the Define-XML file;
%define_write(_cstCreateDisplayStyle=1);

* Validate the Define-XML file;
%cstutilxmlvalidate();

*****;
* Create HTML rendition for browsers that do not allow local rendition of XSLT stylesheet *;
*****;
proc xsl
  in=extxml xsl=xslt out=html;
run;

```

After running this program a results data set will be created which will show if there are any issues (results.definexml_results_adam, see [Appendix 3](#)). After the Define-XML file has been created, it can be reviewed by opening it in a browser. The browser will use the referenced stylesheet to render the XML file as HTML in the browser (Figure 12).

Figure 12 The Define-XML file displayed in a browser

ADaM-IG 1.0

- Analysis Data Reviewer's Guide
- Clinical Study Report
- Statistical Analysis Plan
- ▼ Analysis Results Metadata
 - Table 14-3.01
 - Table 14-5.02
- Analysis Datasets
- Parameter Value Level Metadata
- ▼ Controlled Terminology
 - Controlled Terms
 - External Dictionaries
- Analysis Derivations
- Comments

Date of Define-XML document generation: 2016-03-30T12:22:27-04:00
Stylesheet version: 2016-02-11

| | |
|-----------------------------|--|
| Standard | ADaM-IG 1.0 |
| Study Name | CDISC-Sample |
| Study Description | CDISC-Sample Data Definition |
| Protocol Name | CDISC-Sample |
| Metadata Name | Data Definitions for CDISC-Sample, ADaM-IG 1.0 |
| Metadata Description | Data Definitions for CDISC-Sample, ADaM-IG 1.0 |

Analysis Results Metadata (Summary) for Study CDISC-Sample

[Table 14-3.01](#) Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)

[Dose response analysis for ADAS-Cog changes from baseline](#)
[Pairwise comparisons to placebo for ADAS-Cog changes from baseline](#)

[Table 14-5.02](#) Incidence of Treatment Emergent Serious Adverse Events by Treatment Group

[Incidence of Treatment Emergent Serious Adverse Events by Treatment Group](#)

Analysis Results Metadata (Detail) for Study CDISC-Sample

Table 14-3.01

| Display | Table 14-3.01 Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population) |
|--|---|
| Analysis Result | Dose response analysis for ADAS-Cog changes from baseline |
| Analysis Parameter(s) | PARAMCD = "ACTOT" (Adas-Cog(11) Subscore) |
| Analysis Variable(s) | CHG (Change from Baseline) |
| Analysis Reason | SPECIFIED IN SAP |
| Analysis Purpose | PRIMARY OUTCOME MEASURE |
| Data References (incl. Selection Criteria) | ADQSADAS [PARAMCD = "ACTOT" and AVISIT = "Week 24" and EFFFL = "Y" and ANL01FL = "Y"] |
| Documentation | Linear model analysis of CHG for dose response; using randomized dose (0 for placebo; 54 for low dose; 81 for high dose) and site group in model. Used PROC GLM in SAS to produce p-value (from Type III SS for treatment dose). See page 4 (section 10.1.1) in the Statistical Analysis Plan. Statistical Analysis Plan |
| Programming Statements | [SAS version 9.2] <pre> proc glm data = ADQSADAS; where EFFFL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT"; class SITEGR1; model CHG = TRTPN SITEGR1; run; </pre> |

CONCLUSION

SAS Clinical Standards Toolkit can create a complete Define-XML 2.0 file including Analysis Results Metadata in a convenient way without needing any XML knowledge based on 7 source metadata datasets.

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APPENDIX 1: SOURCE METADATA TABLE STRUCTURES

| source_study | | | | |
|---------------------|-----------------------|--------------------|----------------------|---|
| # | Column Name | Column Type | Column Length | Column Label |
| 1 | sasref | char | 8 | SASreferences sourcedata libref |
| 2 | studyname | char | 128 | Short external name for the study |
| 3 | studydescription | char | 2000 | Description of the study |
| 4 | protocolname | char | 128 | Sponsors internal name for the protocol |
| 5 | formalstandardname | char | 2000 | Formal Name of Standard |
| 6 | formalstandardversion | char | 2000 | Formal Version of Standard |
| 7 | studyversion | char | 128 | Unique study version identifier |
| 8 | standard | char | 20 | Name of Standard |
| 9 | standardversion | char | 20 | Version of Standard |

| source_tables | | | | |
|----------------------|--------------------|--------------------|----------------------|-----------------------------------|
| # | Column Name | Column Type | Column Length | Column Label |
| 1 | sasref | char | 8 | SASreferences sourcedata libref |
| 2 | table | char | 32 | Table Name |
| 3 | label | char | 200 | Table Label |
| 4 | order | num | 8 | Table order |
| 5 | domain | char | 32 | Domain |
| 6 | domaindescription | char | 256 | Domain description |
| 7 | class | char | 40 | Observation Class within Standard |
| 8 | xmlpath | char | 200 | (Relative) path to xpt file |
| 9 | xmltitle | char | 200 | Title for xpt file |
| 10 | structure | char | 200 | Table Structure |
| 11 | purpose | char | 10 | Purpose |
| 12 | keys | char | 200 | Table Keys |
| 13 | state | char | 20 | Data Set State (Final, Draft) |
| 14 | date | char | 20 | Release Date |
| 15 | comment | char | 1000 | Comment |
| 16 | studyversion | char | 128 | Unique study version identifier |
| 17 | standard | char | 20 | Name of Standard |
| 18 | standardversion | char | 20 | Version of Standard |

source_columns

| # | Column Name | Column Type | Column Length | Column Label |
|----|-------------------|-------------|---------------|-----------------------------------|
| 1 | sasref | char | 8 | SASreferences sourcedata libref |
| 2 | table | char | 32 | Table Name |
| 3 | column | char | 32 | Column Name |
| 4 | label | char | 200 | Column Description |
| 5 | order | num | 8 | Column Order |
| 6 | type | char | 1 | Column Type |
| 7 | length | num | 8 | Column Length |
| 8 | displayformat | char | 200 | Display Format |
| 9 | significantdigits | num | 8 | Significant Digits |
| 10 | xmldatatype | char | 18 | XML Data Type |
| 11 | xmlcodelist | char | 128 | SAS Format/XML Codelist |
| 12 | core | char | 10 | Column Required or Optional |
| 13 | origin | char | 40 | Column Origin |
| 14 | origindescription | char | 1000 | Column Origin Description |
| 15 | role | char | 200 | Column Role |
| 16 | algorithm | char | 1000 | Computational Algorithm or Method |
| 17 | comment | char | 1000 | Comment |
| 18 | studyversion | char | 128 | Unique study version identifier |
| 19 | standard | char | 20 | Name of Standard |
| 20 | standardversion | char | 20 | Version of Standard |

source_codelists

| # | Column Name | Column Type | Column Length | Column Label |
|----|---------------------|-------------|---------------|--|
| 1 | sasref | char | 8 | SASreferences sourcedata libref |
| 2 | codelist | char | 128 | Unique identifier for this CodeList |
| 3 | codelistname | char | 128 | CodeList Name |
| 4 | codelistdescription | char | 2000 | CodeList Description |
| 5 | codelistncicode | char | 10 | Codelist NCI Code |
| 6 | codelistdatatype | char | 7 | CodeList item value data type (integer float text string) |
| 7 | sasformatname | char | 32 | SAS format name |
| 8 | codedvaluechar | char | 512 | Value of the codelist item (character) |
| 9 | codedvaluenum | num | 8 | Value of the codelist item (numeric) |
| 10 | decodetext | char | 2000 | Decode value of the codelist item |
| 11 | decodelanguage | char | 17 | Language |
| 12 | codedvaluencicode | char | 10 | Codelist Item NCI Code |
| 13 | rank | num | 8 | CodedValue order relative to other item values |
| 14 | ordernumber | num | 8 | Display order of the item within the CodeList. |
| 15 | extendedvalue | char | 3 | Coded value that has been used to extend external controlled terminology |
| 16 | dictionary | char | 200 | Name of the external codelist |
| 17 | version | char | 200 | Version designator of the external codelist |
| 18 | ref | char | 512 | Reference to a local instance of the dictionary |
| 19 | href | char | 512 | URL of an external instance of the dictionary |
| 20 | studyversion | char | 128 | Unique study version identifier |
| 21 | standard | char | 20 | Name of Standard |
| 22 | standardversion | char | 20 | Version of Standard |

| source_values | | | | |
|----------------------|--------------------|--------------------|----------------------|-----------------------------------|
| # | Column Name | Column Type | Column Length | Column Label |
| 1 | sasref | char | 8 | SASreferences sourcedata libref |
| 2 | table | char | 32 | Table Name |
| 3 | column | char | 32 | Column Name |
| 4 | whereclause | char | 1000 | Where Clause |
| 5 | whereclausecomment | char | 1000 | Where Clause comment |
| 6 | label | char | 200 | Column Description |
| 7 | order | num | 8 | Column Order |
| 8 | type | char | 1 | Column Type |
| 9 | length | num | 8 | Column Length |
| 10 | displayformat | char | 200 | Display Format |
| 11 | significantdigits | num | 8 | Significant Digits |
| 12 | xmldatatype | char | 18 | XML Data Type |
| 13 | xmlodelist | char | 128 | SAS Format/XML Codelist |
| 14 | core | char | 10 | Column Required or Optional |
| 15 | origin | char | 40 | Column Origin |
| 16 | origindescription | char | 1000 | Column Origin Description |
| 17 | role | char | 200 | Column Role |
| 18 | algorithm | char | 1000 | Computational Algorithm or Method |
| 19 | comment | char | 1000 | Comment |
| 20 | studyversion | char | 128 | Unique study version identifier |
| 21 | standard | char | 20 | Name of Standard |
| 22 | standardversion | char | 20 | Version of Standard |

source_documents

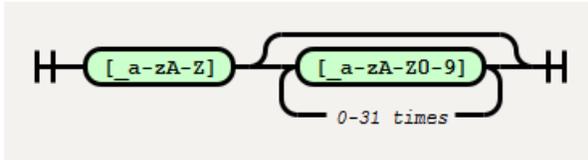
| # | Column Name | Column Type | Column Length | Column Label |
|----|-------------------|-------------|---------------|--|
| 1 | sasref | char | 8 | SASreferences sourcedata libref |
| 2 | doctype | char | 10 | Document Type |
| 3 | href | char | 512 | The pathname and filename of the target dataset relative to the define.xml |
| 4 | title | char | 2000 | Meaningful description, label, or location of the document leaf |
| 5 | pdfpagereftype | char | 16 | Type of Page Reference (PhysicalRef/NamedDestination) |
| 6 | pdfpagerefs | char | 200 | Page Reference |
| 7 | table | char | 32 | Table Name |
| 8 | column | char | 32 | Column Name |
| 9 | whereclause | char | 1000 | Where Clause |
| 10 | displayidentifier | char | 128 | Analysis Display Identifier |
| 11 | resultidentifier | char | 128 | Analysis Display Result Identifier |
| 12 | studyversion | char | 128 | Unique study version identifier |
| 13 | standard | char | 20 | Name of Standard |
| 14 | standardversion | char | 20 | Version of Standard |

| source_analysisresults | | | | |
|-------------------------------|---------------------|--------------------|----------------------|---|
| # | Column Name | Column Type | Column Length | Column Label |
| 1 | sasref | char | 8 | SASreferences sourcedata libref |
| 2 | displayidentifier | char | 128 | Unique identifier for analysis display |
| 3 | displayname | char | 2000 | Title of display |
| 4 | displaydescription | char | 2000 | Description of display |
| 5 | resultidentifier | char | 128 | Specific analysis result within display |
| 6 | resultdescription | char | 2000 | Description of analysis result within display |
| 7 | parametercolumn | char | 8 | Name of the column that holds the parameter |
| 8 | analysisreason | char | 2000 | Reason for analysis |
| 9 | analysispurpose | char | 2000 | Purpose of analysis |
| 10 | tablejoincomment | char | 2000 | Comment describing how to join tables |
| 11 | resultdocumentation | char | 2000 | Documentation of analysis result within display |
| 12 | codecontext | char | 128 | Name and version of computer language |
| 13 | code | char | 2000 | Programming statements |
| 14 | table | char | 32 | Table Name |
| 15 | analysisvariables | char | 1024 | Analysis Variable List |
| 16 | whereclause | char | 1000 | Where Clause |
| 17 | studyversion | char | 128 | Unique Study Version Identifier |
| 18 | standard | char | 20 | Name of Standard |
| 19 | standardversion | char | 20 | Version of Standard |

APPENDIX 2: RAILROAD DIAGRAM DEFINING THE WHERECLAUSE SYNTAX

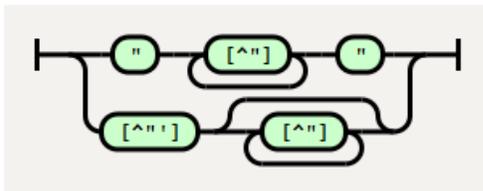
DOMAIN VARIABLE

A letter or underscore followed by 0 to 31 letters, digits or underscores
Notice that CDISC currently has stricter rules, since it only allows 8 characters.

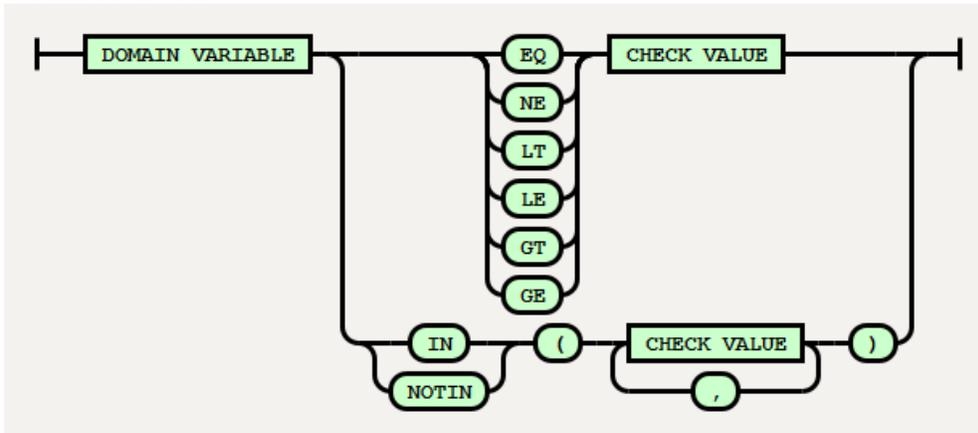


CHECK VALUE

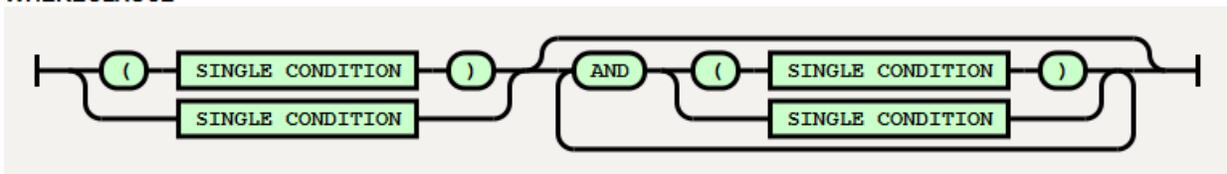
A non-empty string without a double quote enclosed in double quotes, or a character that is not a single or double quote, followed by a string without a double quote. The latter includes the representation of numbers.



SINGLE CONDITION



WHERECLAUSE



This diagram was created with the Railroad Diagram Generator, a small JS+SVG library for drawing railroad syntax diagrams by Tab Atkins Jr., which can be found online at <https://github.com/tabatkins/railroad-diagrams>.

APPENDIX 3: RESULTS DATA SET

| | resultid | srcdata | message | resultseverity |
|----|----------|---------------------------------|--|----------------|
| 1 | CST0108 | CST_SETPROPERTIES | The properties were processed from the PATH c:\cstGlobalLibrary\standards\cst-framework-1.7\programs\initialize.properties | Info |
| 2 | CST0200 | CST_CREATEDSFROMTEMPLATE | The SAS libref cstmplt was allocated to c:\cstGlobalLibrary\standards\cst-framework-1.7\templates to perform the template lookup | Info |
| 3 | CST0102 | CST_CREATEDSFROMTEMPLATE | work.sasreferences (SAS File and Library References) was created as requested | Info |
| 4 | CST0200 | CSTUTIL_PROCESSETUP | Process setup is using this SASReferences: C:\Users\frjans\AppData\Local\Temp\SAS Temporary Files_TD1928_L77359_sasreferences | Info |
| 5 | CST0200 | CST_INSERTSTANDARDASREFS | SASReferences data set was successfully validated | Info |
| 6 | CST0200 | CSTUTIL_ALLOCATESASREFERENCES | SASReferences data set was successfully validated | Info |
| 7 | CST0108 | CST_SETPROPERTIES | The properties were processed from the PATH c:\cstGlobalLibrary\standards\cdisc-definexml-2.0.0-1.7\programs\initialize.properties | Info |
| 8 | CST0200 | DEFINE_SOURCECETODEFINE | PROCESS STANDARD: CDISC-DEFINE-XML | Info |
| 9 | CST0200 | DEFINE_SOURCECETODEFINE | PROCESS STANDARDVERSION: 2.0.0 | Info |
| 10 | CST0200 | DEFINE_SOURCECETODEFINE | PROCESS DRIVER: create_definexml_from_source_adam.sas | Info |
| 11 | CST0200 | DEFINE_SOURCECETODEFINE | PROCESS DATE: 2016-02-24T12:57:43 | Info |
| 12 | CST0200 | DEFINE_SOURCECETODEFINE | PROCESS TYPE: SOURCE TO DEFINE-XML | Info |
| 13 | CST0200 | DEFINE_SOURCECETODEFINE | PROCESS SASREFERENCES: C:\Users\frjans\AppData\Local\Temp\SAS Temporary Files_TD1928_L77359_sasreferences | Info |
| 14 | CST0200 | DEFINE_SOURCECETODEFINE | PROCESS STUDYROOTPATH: c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\sascdemodata | Info |
| 15 | CST0200 | DEFINE_SOURCECETODEFINE | PROCESS STUDYOUTPUTPATH: c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7 | Info |
| 16 | CST0200 | DEFINE_SOURCECETODEFINE | PROCESS GLOBALLIBRARY: c:\cstGlobalLibrary | Info |
| 17 | CST0200 | DEFINE_SOURCECETODEFINE | PROCESS CSTVERSION: 1.7 | Info |
| 18 | CST0122 | CST_CREATETABLESFORDATASTANDARD | The tables were created for CDISC-DEFINE-XML 2.0.0 in library srodata | Info |
| 19 | CST0102 | DEFINE_SOURCECSTUDY | srodata.DefineDocument was created as requested (1 record) | Info |
| 20 | CST0102 | DEFINE_SOURCECSTUDY | srodata.Study was created as requested (1 record) | Info |
| 21 | CST0102 | DEFINE_SOURCECSTUDY | srodata.MetaDataVersion was created as requested (1 record) | Info |
| 22 | CST0102 | DEFINE_SOURCECTABLES | srodata.ItemGroupDefs was created as requested (3 records) | Info |
| 23 | CST0102 | DEFINE_SOURCECTABLES | srodata.CommentDefs was created as requested (3 records) | Info |
| 24 | CST0102 | DEFINE_SOURCECTABLES | srodata.TranslatedText was created as requested (3 records) | Info |
| 25 | CST0102 | DEFINE_SOURCECTABLES | srodata.TranslatedText was created as requested (6 records) | Info |
| 26 | CST0102 | DEFINE_SOURCECTABLES | srodata.Aliases was created as requested (0 records) | Info |
| 27 | CST0102 | DEFINE_SOURCECTABLES | srodata.ItemGroupLeaf was created as requested (3 records) | Info |
| 28 | CST0102 | DEFINE_SOURCECTABLES | srodata.ItemGroupLeafTitles was created as requested (3 records) | Info |
| 29 | CST0102 | DEFINE_SOURCECOLUMNS | srodata.ItemDefs was created as requested (143 records) | Info |
| 30 | CST0102 | DEFINE_SOURCECOLUMNS | srodata.MethodDefs was created as requested (54 records) | Info |
| 31 | CST0102 | DEFINE_SOURCECOLUMNS | srodata.CommentDefs was created as requested (15 records) | Info |
| 32 | CST0102 | DEFINE_SOURCECOLUMNS | srodata.ItemGroupItemRefs was created as requested (143 records) | Info |
| 33 | CST0102 | DEFINE_SOURCECOLUMNS | srodata.TranslatedText was created as requested (149 records) | Info |
| 34 | CST0102 | DEFINE_SOURCECOLUMNS | srodata.TranslatedText was created as requested (161 records) | Info |
| 35 | CST0102 | DEFINE_SOURCECOLUMNS | srodata.TranslatedText was created as requested (215 records) | Info |
| 36 | CST0102 | DEFINE_SOURCECOLUMNS | srodata.TranslatedText was created as requested (288 records) | Info |
| 37 | CST0102 | DEFINE_SOURCECOLUMNS | srodata.ItemOrigin was created as requested (140 records) | Info |
| 38 | CST0102 | DEFINE_SOURCECODELISTS | srodata.CodeLists was created as requested (29 records) | Info |
| 39 | CST0102 | DEFINE_SOURCECODELISTS | srodata.TranslatedText was created as requested (317 records) | Info |
| 40 | CST0102 | DEFINE_SOURCECODELISTS | srodata.EnumeratedItems was created as requested (98 records) | Info |
| 41 | CST0102 | DEFINE_SOURCECODELISTS | srodata.CodeListItems was created as requested (97 records) | Info |
| 42 | CST0102 | DEFINE_SOURCECODELISTS | srodata.TranslatedText was created as requested (414 records) | Info |
| 43 | CST0102 | DEFINE_SOURCECODELISTS | srodata.ExternalCodeLists was created as requested (1 record) | Info |
| 44 | CST0102 | DEFINE_SOURCECODELISTS | srodata.Aliases was created as requested (12 records) | Info |
| 45 | CST0102 | DEFINE_SOURCECODELISTS | srodata.Aliases was created as requested (32 records) | Info |
| 46 | CST0102 | DEFINE_SOURCECODELISTS | srodata.Aliases was created as requested (45 records) | Info |
| 47 | DEF0097 | DEFINEUTIL_VALIDATEWHERECLAUSE | Validating WhereClause in sampdata.source_values (creating _cstSourceValues1_1376) | Info |
| 48 | DEF0097 | DEFINEUTIL_VALIDATEWHERECLAUSE | There were no issues with WhereClause in sampdata.source_values | Info |
| 49 | CST0102 | DEFINE_SOURCEVALUES | srodata.ItemDefs was created as requested (149 records) | Info |
| 50 | CST0102 | DEFINE_SOURCEVALUES | srodata.MethodDefs was created as requested (56 records) | Info |
| 51 | CST0102 | DEFINE_SOURCEVALUES | srodata.CommentDefs was created as requested (18 records) | Info |
| 52 | CST0102 | DEFINE_SOURCEVALUES | srodata.ValueLists was created as requested (3 records) | Info |
| 53 | CST0102 | DEFINE_SOURCEVALUES | srodata.ValueListItemRefs was created as requested (6 records) | Info |
| 54 | CST0102 | DEFINE_SOURCEVALUES | srodata.ItemValueListRefs was created as requested (3 records) | Info |
| 55 | CST0102 | DEFINE_SOURCEVALUES | srodata.ItemRefWhereClauseRefs was created as requested (6 records) | Info |
| 56 | CST0102 | DEFINE_SOURCEVALUES | srodata.WhereClauseDefs was created as requested (6 records) | Info |
| 57 | CST0102 | DEFINE_SOURCEVALUES | srodata.WhereClauseRangeChecks was created as requested (6 records) | Info |
| 58 | CST0102 | DEFINE_SOURCEVALUES | srodata.WhereClauseRangeCheckValues was created as requested (19 records) | Info |
| 59 | CST0102 | DEFINE_SOURCEVALUES | srodata.TranslatedText was created as requested (420 records) | Info |
| 60 | CST0102 | DEFINE_SOURCEVALUES | srodata.TranslatedText was created as requested (423 records) | Info |
| 61 | CST0102 | DEFINE_SOURCEVALUES | srodata.TranslatedText was created as requested (425 records) | Info |
| 62 | CST0102 | DEFINE_SOURCEVALUES | srodata.TranslatedText was created as requested (426 records) | Info |
| 63 | CST0102 | DEFINE_SOURCEVALUES | srodata.ItemOrigin was created as requested (146 records) | Info |
| 64 | DEF0097 | DEFINEUTIL_VALIDATEWHERECLAUSE | Validating WhereClause in _cstSourceAnalysisResults_3900 (creating _cstSourceAnalysisResults_3900) | Info |
| 65 | DEF0097 | DEFINEUTIL_VALIDATEWHERECLAUSE | There were no issues with WhereClause in _cstSourceAnalysisResults_3900 | Info |
| 66 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srodata.analysisresultdisplays was created as requested (2 records) | Info |
| 67 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srodata.analysisresults was created as requested (3 records) | Info |
| 68 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srodata.analysisdatasets was created as requested (3 records) | Info |
| 69 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srodata.analysisdataset was created as requested (4 records) | Info |
| 70 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srodata.analysiswhereclauserefs was created as requested (4 records) | Info |
| 71 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srodata.analysisvariables was created as requested (4 records) | Info |
| 72 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srodata.analysisdocumentation was created as requested (3 records) | Info |
| 73 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srodata.analysisprogrammingcode was created as requested (3 records) | Info |
| 74 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srodata.WhereClauseDefs was created as requested (10 records) | Info |
| 75 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srodata.WhereClauseRangeChecks was created as requested (17 records) | Info |
| 76 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srodata.WhereClauseRangeCheckValues was created as requested (30 records) | Info |
| 77 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srodata.TranslatedText was created as requested (428 records) | Info |
| 78 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srodata.TranslatedText was created as requested (431 records) | Info |
| 79 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srodata.TranslatedText was created as requested (434 records) | Info |
| 80 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srodata.TranslatedText was created as requested (437 records) | Info |

| | | | | |
|-----|---------|---------------------------------|---|------|
| 81 | CST0102 | DEFINE_SOURCEANALYSISRESULTS | srcdata.CommentDefs was created as requested (19 records) | Info |
| 82 | DEF0097 | DEFINEUTIL_VALIDATEWHERECLAUSE | Validating WhereClause in sampdata.source_documents (creating _cstSourceDocuments_2569) | Info |
| 83 | DEF0097 | DEFINEUTIL_VALIDATEWHERECLAUSE | There were no issues with WhereClause in sampdata.source_documents | Info |
| 84 | DEF0097 | DEFINEUTIL_VALIDATEWHERECLAUSE | Validating WhereClause in sampdata.source_values (creating _cstSourceValues1_2569) | Info |
| 85 | DEF0097 | DEFINEUTIL_VALIDATEWHERECLAUSE | There were no issues with WhereClause in sampdata.source_values | Info |
| 86 | CST0102 | DEFINE_SOURCEDOCUMENTS | srcdata.AnnotatedCRFs was created as requested (0 records) | Info |
| 87 | CST0102 | DEFINE_SOURCEDOCUMENTS | srcdata.SupplementalDocs was created as requested (3 records) | Info |
| 88 | CST0102 | DEFINE_SOURCEDOCUMENTS | srcdata.MDVLeaf was created as requested (8 records) | Info |
| 89 | CST0102 | DEFINE_SOURCEDOCUMENTS | srcdata.MDVLeafTitles was created as requested (8 records) | Info |
| 90 | CST0102 | DEFINE_SOURCEDOCUMENTS | srcdata.DocumentRefs was created as requested (14 records) | Info |
| 91 | CST0102 | DEFINE_SOURCEDOCUMENTS | srcdata.PDFPageRefs was created as requested (8 records) | Info |
| 92 | CST0102 | CSTUTIL_SAVERESULTS | results.sourcetodefinexml_adam_results was created as requested | Info |
| 93 | CST0200 | CSTUTIL_ALLOCATESASREFERENCES | PROCESS STANDARD: | Info |
| 94 | CST0200 | CSTUTIL_ALLOCATESASREFERENCES | PROCESS STANDARDVERSION: | Info |
| 95 | CST0200 | CSTUTIL_ALLOCATESASREFERENCES | PROCESS DRIVER: create_definexml_from_source_adam.sas | Info |
| 96 | CST0200 | CSTUTIL_ALLOCATESASREFERENCES | PROCESS DATE: 2016-02-24T12:57:49 | Info |
| 97 | CST0200 | CSTUTIL_ALLOCATESASREFERENCES | PROCESS TYPE: FILEIO | Info |
| 98 | CST0200 | CSTUTIL_ALLOCATESASREFERENCES | PROCESS SASREFERENCES: C:\Users\vfjans\AppData\Local\Temp\SAS Temporary Files_TD1928_L77359_cstasrefs.sas7bdat | Info |
| 99 | CST0200 | CSTUTIL_ALLOCATESASREFERENCES | PROCESS STUDYROOTPATH: c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\sascstdemodata | Info |
| 100 | CST0200 | CSTUTIL_ALLOCATESASREFERENCES | PROCESS STUDYOUTPUTPATH: c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7 | Info |
| 101 | CST0200 | CSTUTIL_ALLOCATESASREFERENCES | PROCESS GLOBALLIBRARY: c:\cstGlobalLibrary | Info |
| 102 | CST0200 | CSTUTIL_ALLOCATESASREFERENCES | PROCESS CSTVERSION: 1.7 | Info |
| 103 | CST0122 | CST_CREATETABLESFORDATASTANDARD | The tables were created for CDISC-DEFINE-XML 2.0.0 in library _cst7298 | Info |
| 104 | CST0200 | JAVA CHECK | No Java issues | Info |
| 105 | CST0200 | CST_CREATEDSFROMTEMPLATE | The SAS libref csttmplt was allocated to c:\cstGlobalLibrary\standards\cst-framework-1.7\templates to perform the template lookup | Info |
| 106 | CST0102 | CST_CREATEDSFROMTEMPLATE | work._cstxmllog (Results) was created as requested | Info |
| 107 | CST0191 | XML TRANSFORMER | Transform starting. | Info |
| 108 | CST0191 | XML TRANSFORMER | Using JRE: C:\PROGRAMS\SASHome\SASPRI\19.4\jre | Info |
| 109 | CST0191 | XML TRANSFORMER PARAMETER | Import Or Export: EXPORT | Info |
| 110 | CST0191 | XML TRANSFORMER PARAMETER | Standards XML Path: c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\sourcexml\define-adam-2.1.xml | Info |
| 111 | CST0191 | XML TRANSFORMER PARAMETER | Fail on Validation Error: false | Info |
| 112 | CST0191 | XML TRANSFORMER PARAMETER | Standard Name: CDISC-DEFINE-XML | Info |
| 113 | CST0191 | XML TRANSFORMER PARAMETER | Standard Version: 2.0.0 | Info |
| 114 | CST0191 | XML TRANSFORMER PARAMETER | Schema Repository Location: c:\cstGlobalLibrary/schema-repository | Info |
| 115 | CST0191 | XML TRANSFORMER PARAMETER | XSL Repository Location: c:\cstGlobalLibrary/xsl-repository | Info |
| 116 | CST0191 | XML TRANSFORMER PARAMETER | Output Encoding: UTF-8 | Info |
| 117 | CST0191 | XML TRANSFORMER PARAMETER | Log File Location: C:\Users\vfjans\AppData\Local\Temp\SAS Temporary Files_TD1928_L77359_log4919_write.xml | Info |
| 118 | CST0191 | XML TRANSFORMER PARAMETER | Header Comment Text: Produced from SAS data using the SAS Clinical Standards Toolkit 1.7 | Info |
| 119 | CST0191 | XML TRANSFORMER PARAMETER | Is Validating XML: true | Info |
| 120 | CST0191 | XML TRANSFORMER PARAMETER | Creating Display Stylesheet: true | Info |
| 121 | CST0191 | XML TRANSFORMER PARAMETER | Custom Stylesheet: c:\cstGlobalLibrary\standards\cdisc-definexml-2.0.0-1.7\stylesheet\define2-0-0.xml | Info |
| 122 | CST0191 | XML TRANSFORMER PARAMETER | Custom Stylesheet Output Shortname: define2-0-0.xml | Info |
| 123 | CST0191 | XML TRANSFORMER PARAMETER | Creating Output Folders: true | Info |
| 124 | CST0191 | XML TRANSFORMER | Transform complete. | Info |
| 125 | CST0191 | XML TRANSFORMER | Transform time: 1125 ms. | Info |
| 126 | CST0191 | XML TRANSFORMER PARAMETER | XML File to Validate: c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\sourcexml\define-adam-2.1.xml | Info |
| 127 | CST0191 | XML TRANSFORMER PARAMETER | Schema being validated against: c:\cstGlobalLibrary/schema-repository\cdisc-am-1.0/am1-0-0.xsd | Info |
| 128 | CST0191 | XML TRANSFORMER | The document validated successfully | Info |
| 129 | DEF0010 | DEFINE_WRITE | The DEFINE-XML file was created at c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\sourcexml\define-adam-2.1.xml | Info |
| 130 | CST0102 | CSTUTIL_SAVERESULTS | results.sourcetodefinexml_adam_results was created as requested | Info |
| 131 | CST0200 | CSTUTILXMLVALIDATE | Starting XML Validation | Info |
| 132 | CST0200 | JAVA CHECK | No Java issues | Info |
| 133 | CST0200 | CST_CREATEDSFROMTEMPLATE | The SAS libref csttmplt was allocated to c:\cstGlobalLibrary\standards\cst-framework-1.7\templates to perform the template lookup | Info |
| 134 | CST0102 | CST_CREATEDSFROMTEMPLATE | work._cstxmllog (Results) was created as requested | Info |
| 135 | CST0191 | XML TRANSFORMER | Transform starting. | Info |
| 136 | CST0191 | XML TRANSFORMER | Using JRE: C:\PROGRAMS\SASHome\SASPRI\19.4\jre | Info |
| 137 | CST0191 | XML TRANSFORMER PARAMETER | Import Or Export: EXPORT | Info |
| 138 | CST0191 | XML TRANSFORMER PARAMETER | Standards XML Path: c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\sourcexml\define-adam-2.1.xml | Info |
| 139 | CST0191 | XML TRANSFORMER PARAMETER | Fail on Validation Error: false | Info |
| 140 | CST0191 | XML TRANSFORMER PARAMETER | Standard Name: CDISC-DEFINE-XML | Info |
| 141 | CST0191 | XML TRANSFORMER PARAMETER | Standard Version: 2.0.0 | Info |
| 142 | CST0191 | XML TRANSFORMER PARAMETER | Schema Repository Location: c:\cstGlobalLibrary/schema-repository | Info |
| 143 | CST0191 | XML TRANSFORMER PARAMETER | XSL Repository Location: null | Info |
| 144 | CST0191 | XML TRANSFORMER PARAMETER | Output Encoding: UTF-8 | Info |
| 145 | CST0191 | XML TRANSFORMER PARAMETER | Log File Location: C:\Users\vfjans\AppData\Local\Temp\SAS Temporary Files_TD1928_L77359_log9387_xmlvalidate.xml | Info |
| 146 | CST0191 | XML TRANSFORMER PARAMETER | Header Comment Text: Produced from SAS data using the SAS Clinical Standards Toolkit | Info |
| 147 | CST0191 | XML TRANSFORMER PARAMETER | Is Validating XML: true | Info |
| 148 | CST0191 | XML TRANSFORMER PARAMETER | Creating Display Stylesheet: false | Info |
| 149 | CST0191 | XML TRANSFORMER PARAMETER | Custom Stylesheet: null | Info |
| 150 | CST0191 | XML TRANSFORMER PARAMETER | Custom Stylesheet Output Shortname: null | Info |
| 151 | CST0191 | XML TRANSFORMER PARAMETER | Creating Output Folders: true | Info |
| 152 | CST0191 | XML TRANSFORMER PARAMETER | XML File to Validate: c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\sourcexml\define-adam-2.1.xml | Info |
| 153 | CST0191 | XML TRANSFORMER PARAMETER | Schema being validated against: c:\cstGlobalLibrary/schema-repository\cdisc-am-1.0/am1-0-0.xsd | Info |
| 154 | CST0191 | XML TRANSFORMER | The document validated successfully | Info |
| 155 | CST0100 | CSTUTIL_APPENDRESULTDS | No errors detected in the XML file | Info |
| 156 | CST0102 | CSTUTIL_SAVERESULTS | results.sourcetodefinexml_adam_results was created as requested | Info |