SAS® Clinical Standards Toolkit: define.xml and Value Level Metadata

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presented by Gene Lightfoot

SAS Institute Inc.
Agenda

- What is define.xml (CRT-DDS)?
- The CRT-DDS SAS Data Model
- What is SAS Clinical Standards Toolkit (CST)?
- Create define.xml from SDTM 3.1.2 metadata
- Implementing Value Level Metadata
What is the define.xml (CRT-DDS)?

- Case Report Tabulation Data Specification (CRT-DDS, or define.xml): Production version: 1.0.0
  CRT-DDS 1.0.0 is the only production version right now

- Extension of the CDISC Operational Data Model (ODM), an XML specification to facilitate the archival and interchange of the metadata and data for clinical research

- Maintained by CDISC’s XML Technologies Team (formerly known as the ODM team)

- New Define-XML v2.0 released soon with additional metadata support (based on ODM 1.3.1)
Define.XML

FDA Adds CDISC ODM Define.xml to Study Data Specifications

The FDA has now included the CDISC Case Report Tabulation Data Definition Specification (define.xml), which is based on the CDISC ODM, as part of the eCTD Study Data Specifications for the eCTD for submissions using the SDTM. The revised specifications are available here.

Case Report Tabulation Data Definition Specification (CRT-DDS, also called define.xml)
Final Version 1.0

CRT-DDS Released for Implementation February 10, 2005.

The CDISC define.xml Team has published the Case Report Tabulation Data Definition Specification (define.xml) Version 1.0 for
What is the define.xml (CRT-DDS)?

The specifications

http://www.cdisc.org/define-xml

Case Report Tabulation Data Definition Specification (define.xml)
Prepared by the CDISC define.xml Team

Notes to Readers
This version of the Case Report Tabulation Data Definition Specification supersedes all prior versions. Version 1.0.0 reflects changes from a comment period through the Health Level 7 (HL7) Regulated Clinical Research Information Management Technical Committee (RCRIM) in December 2003 (www.hl7.org) and CDISC’s website in September 2004 as well as the work done by the define.xml team to add modularity, features, and additional documentation.
Version 1.0.0 incorporated the applicable comments, suggestions, and corrections received from the two comment periods specified above and is the initial implementation version.

Revision History
<table>
<thead>
<tr>
<th>Date</th>
<th>Version</th>
<th>Summary of Changes</th>
<th>Primary Author(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005-01-27</td>
<td>1.0.0</td>
<td>This is the official implementation version of the Case Report Tabulation Data Definition specification.</td>
<td>Anthony Ogback, William Ogback, Sally Carcella, and the define.xml team</td>
</tr>
<tr>
<td>2005-01-29</td>
<td>1.0.0</td>
<td>Administrative update.</td>
<td></td>
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</table>

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An official copy of this document is available at http://www.cdisc.org/models/define1.2/ODM/1.2-0.html
What is the define.xml (CRT-DDS)?

Metadata Submission Guidelines
What is the define.xml (CRT-DDS)?

XML Schemas in Simple Terms

- Defines elements, attributes, data types etc. and their relationships
- Provides the specification for an XML document
- Enables validation of XML documents

Important: an XML schema is not able to verify all business rules in the specification!!
What is the define.xml (CRT-DDS)?

http://www.cdisc.org/define-xml

Define.XML

XML Schema Validation for Define.xml White Paper

The XML Schema Validation for Define.xml white paper provides guidance on validating define.xml version 1.0 documents against the define.xml XML schemas. It proposes practices and tools to improve define.xml schema validation. The goal is to foster more consistent validation results in order to facilitate regulatory submissions and interchange of define.xml documents. The document does not include any define.xml specifications or recommendations for creating define.xml content.

XML Schema Validation for Define.xml (pdf)

This zip file packages 3 define.xml version 1.0 examples with copies of the schemas for testing define.xml validation.

Define.xml Validation (zip)
define.xml – content - metadata

- Domain Level metadata
- Variable Level metadata
- Value Level metadata
- Code List metadata
- Computational Methods metadata
- Documents metadata (aCRF)
<ItemGroupDef
    OID="IG.MH" Name="MH" Repeating="Yes"
    IsReferenceData="No"
    SASDatasetName="MH"
    Purpose="Tabulation"
    def:Label="Medical History"
    def:Structure="One record per medical history event per subject"
    def:DomainKeys="STUDYID, USUBJID, MHCAT, MHTERM, MHSTDTC"
    def:Class="EVENTS"
    def:ArchiveLocationID="#Location.MH">

    <ItemRef ItemOID="#I.STUDYID"
        OrderNumber="1" Mandatory="Yes" Role="IDENTIFIER" />
    <ItemRef ItemOID="#I.DOMAIN"
        OrderNumber="2" Mandatory="Yes" Role="IDENTIFIER" />
    <ItemRef ItemOID="#I.USUBJID"
        OrderNumber="3" Mandatory="Yes" Role="IDENTIFIER" />

    ...
    <ItemRef ItemOID="#I.MHTERM"
        OrderNumber="8" Mandatory="Yes" Role="TOPIC" />
    ...

    <def:leaf ID="#Location.MH" xlink:href="mh.xpt">
        <def:title>mh.xpt</def:title>
    </def:leaf>
</ItemGroupDef>
define.xml – Variable level metadata

<ItemRef ItemOID="I.VSTESTCD" OrderNumber="6" Mandatory="Yes" Role="TOPIC" RoleCodeListOID="RoleCodeList" />

<ItemRef ItemOID="I.VSBLFL" OrderNumber="14" Mandatory="No" Role="RECORD QUALIFIER" RoleCodeListOID="RoleCodeList" />

<ItemDef OID="I.VSTESTCD"
  Name="VSTESTCD" DataType="text"
  Length="8" Origin="CRF Page 9"
  def:Label="Vital Signs Test Short Name">
  <def:ValueListRef ValueListOID="VL.VSTESTCD" />
</ItemDef>

...

<ItemDef OID="I.VSBLFL" Name="VSBLFL" DataType="text" Length="1"
  Origin="DERIVED" Comment="Derivation of baseline: Safety patients only: VSBLFL=Y for last non missing record on or before the first dose date (RFSTDTC)."
  def:Label="Baseline Flag"
  def:ComputationMethodOID="CM.VSBLFL">
  <CodeListRef CodeListOID="CL.NY" />
</ItemDef>
What is the define.xml (CRT-DDS)?

• define.xml contains **metadata** and is **machine** readable
• define.xml becomes **human** readable with a **stylesheet**
• The stylesheet is for display, but is **not** the standard.
**What is the define.xml (CRT-DDS)?**

**define.xml** becomes **human readable with an XSL stylesheet**

<table>
<thead>
<tr>
<th>Dataset</th>
<th>Description</th>
<th>Structure</th>
<th>Purpose</th>
<th>Keys</th>
<th>Location</th>
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<td>DM</td>
<td>Demographics</td>
<td>Special Purpose - One record per event per subject</td>
<td>Tabulation</td>
<td>STUDYID, USUBJID</td>
<td>c:nets/1234_dmn.xpt</td>
</tr>
<tr>
<td>TE</td>
<td>Trial Elements</td>
<td>Trial Design - One Record Per Element</td>
<td>Tabulation</td>
<td>STUDYID, ELEMENT</td>
<td>c:nets/1234_te.xpt</td>
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<tr>
<td>TA</td>
<td>Trial Arms</td>
<td>Trial Design - One Record per Element for each Arm</td>
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<td>c:nets/1234_ta.xpt</td>
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<tr>
<td>SE</td>
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<td>c:nets/1234_se.xpt</td>
</tr>
<tr>
<td>SV</td>
<td>Subject Visits</td>
<td>Study Design - One Record Per Subject Visit</td>
<td>Tabulation</td>
<td>STUDYID, VISIT</td>
<td>c:nets/1234_sv.xpt</td>
</tr>
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<td>EX</td>
<td>Exposure</td>
<td>Interventions - One record per constant dosing interval per subject</td>
<td>Tabulation</td>
<td>USUBJID, EXRT, EXSEQ</td>
<td>c:nets/1234_ex.xpt</td>
</tr>
<tr>
<td>CM</td>
<td>Concomitant Medications</td>
<td>Interventions - One record per event per subject</td>
<td>Tabulation</td>
<td>USUBJID, CMRT, CMSEQ</td>
<td>c:nets/1234_cm.xpt</td>
</tr>
<tr>
<td>SU</td>
<td>Substance Use</td>
<td>Interventions - One record per substance use type per subject</td>
<td>Tabulation</td>
<td>USUBJID, SUTRT, SUSEQ</td>
<td>c:nets/1234_su.xpt</td>
</tr>
<tr>
<td>AE</td>
<td>Adverse Events</td>
<td>Events - One record per event per subject</td>
<td>Tabulation</td>
<td>USUBJID, AETERM, AESEQ</td>
<td>c:nets/1234_ae.xpt</td>
</tr>
<tr>
<td>DS</td>
<td>Disposition</td>
<td>Events - One record per disposition status or protocol milestone per subject</td>
<td>Tabulation</td>
<td>USUBJID, DSTERM, DSSEQ</td>
<td>c:nets/1234_ds.xpt</td>
</tr>
<tr>
<td>MH</td>
<td>Medical History</td>
<td>Events - One record per event per subject</td>
<td>Tabulation</td>
<td>USUBJID, MHTERM, MHSEQ</td>
<td>c:nets/1234_mh.xpt</td>
</tr>
<tr>
<td>EG</td>
<td>ECG Test Results</td>
<td>Findings - One record per event per subject</td>
<td>Tabulation</td>
<td>USUBJID, EGTESTCD, EGSEQ</td>
<td>c:nets/1234_eg.xpt</td>
</tr>
<tr>
<td>IE</td>
<td>Inclusion/Exclusion Exceptions</td>
<td>Findings - One record per event per subject</td>
<td>Tabulation</td>
<td>USUBJID, IETEST, IESEQ</td>
<td>c:nets/1234_ie.xpt</td>
</tr>
<tr>
<td>LB</td>
<td>Laboratory Tests</td>
<td>Findings - One record per lab test per subject</td>
<td>Tabulation</td>
<td>USUBJID, LBTESTCD, VISITNUM, TPTNUM, LBSEQ</td>
<td>c:nets/1234_lb.xpt</td>
</tr>
</tbody>
</table>
What is the define.xml (CRT-DDS)?

... and looks even fancier with a different stylesheet.
The CRT-DDS SAS Data Model
The CRT-DDS SAS Data Model

- `define.xml` has a deep hierarchy
- `define.xml` contains many relations

```xml
<ItemGroupDef OID="MH"
    Name="MH" Repeating="Yes" IsReferenceData="No"
    Purpose="Tabulation" def:Label="Medical History"
    def:Structure="One record per medical history event per subject"
    def:DomainKeys="STUDYID, USUBJID, MHCAT, MHTERM, MHSTDTC"
    def:Class="EVENTS" def:ArchiveLocationID="Location.AE">
    <ItemRef ItemOID="STUDYID" OrderNumber="1" Mandatory="Yes"
        Role="IDENTIFIER" RoleCodeListOID="RoleCodeList" />
</ItemGroupDef>

...<def:leaf ID="Location.MH" xlink:href="mh.xpt">
    <def:title>mh.xpt</def:title>
</def:leaf>
</ItemGroupDef>

...<ItemDef OID="STUDYID" Name="STUDYID" DataType="text" Length="7"
    Origin="CRF Page 3" def:Label="Study Identifier" />
```
The CRT-DDS SAS Data Model

- SAS provides data model that represents CRT-DDS Version 1.0 format in 39 SAS data sets. 20 of these are typically used for the define.xml (*).
- Patterned to match the XML element and attribute structure of the define.xml file.
- XML element → SAS dataset
  XML attribute → SAS variable
The CRT-DDS SAS Data Model

```xml
<ItemDef OID="COL10" Name="BRTHDTC" DataType="text" Length="64"
  SASFieldName="BRTHDTC" def:Label="Date/Time of Birth"/>
<ItemDef OID="COL11" Name="AGE" DataType="float"
  Length="8" SASFieldName="AGE" def:Label="Age"/>
<ItemDef OID="COL12" Name="AGEU" DataType="text"
  Length="10" SASFieldName="AGEU" def:Label="Age Units">
  <CodeListRef CodeListOID="AGEU"/>
</ItemDef>
```

<table>
<thead>
<tr>
<th>VIEWTABLE: sywork.Itemdefs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OID</strong></td>
</tr>
<tr>
<td>--------</td>
</tr>
<tr>
<td>10</td>
</tr>
<tr>
<td>11</td>
</tr>
<tr>
<td>12</td>
</tr>
</tbody>
</table>
What is the SAS Clinical Standards Toolkit (CST)?
What is the SAS Clinical Standards Toolkit?

- Framework to primarily support clinical research activities.
- Initially focusing on standards as defined by CDISC, but not limited to CDISC.
- A collection of “tools”, providing an initial set of standards and functionality that is evolving and growing with updates and releases.
- Designed as an integral part of Clinical Data Integration (CDI), but is available to all SAS users as open source SAS Macros.
What is the SAS Clinical Standards Toolkit?

- CDISC SDTM models available 3.1.1 and 3.1.2
- ADaM support
- Controlled Terminology (NCI)
- CRT-DDS (define.xml) capability
- ODM 1.3 import/export
- Flexible: customizable to fit various standards (there is no 'magic bullet' !)
- Available at no additional charge for SAS/Base customers
SDTM metadata → define.xml
CST typical program

- Define global macro variables ("properties")
  - `%cst_setStandardProperties(_cstStandard=CST-FRAMEWORK,_cstSubType=initialize);`

- Define inputs / outputs (libnames, filenames, SAS autocall macros, ...)
  - 1. Create SASReferences dataset
  - 2. `%cstutil_processsetup();`
    (default: use WORK.SASReferences)

- Run process specific macro:
  - `%crtdds_sdtmttodefine`
  - `%crtdds_validate`
  - `%crtdds_write`
  - `%crtdds_xmlvalidate`
  - `%crtdds_read`
CRT-DDS macros for creating define.xml

- `%crtdds_sdtmtodefinedefine` – Create empty CRT-DDS SAS data sets and populates them based on SDTM sourcemetadata

- `%crtdds_validate` – Validate CRT-DDS SAS data sets

- `%crtdds_write` – Create define.xml from CRT-DDS SAS data sets

- `%crtdds_xmlvalidate` – Validate define.xml against XML schema
CRT-DDS macros for creating define.xml

- `%crtdds_sdtmtodedefine` –
  Create 39 empty CRT-DDS SAS data sets and populates a selection of them based on SDTM sourcemetadata

- 20 of the 39 CRT-DDS datasets are needed for creating the define.xml for submission

- CST 1.4: `%crtdds_sdtmtodedefine` will populate 12 of these data sets (no Value Level Metadata)

- CST 1.5: `%crtdds_sdtmtodedefine` will populate all of the 20 data sets using more SDTM source metadata (including Value Level Metadata)
**SDTM to define.xml**

SAS representation of CRT-DDS
(39 SAS data sets)

1. **Table Study Metadata**
2. **Column Study Metadata**
3. **Validation Process**
4. **XML Validation Process**
5. **Other Study Metadata**
   - Value Level Metadata
   - aCRF reference...

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### VIEWTABLE: Sdtmmeta.Source_study (Source Study Metadata)

<table>
<thead>
<tr>
<th>definedocumentname</th>
<th>sasref</th>
<th>studyname</th>
<th>protocolname</th>
<th>studydescription</th>
</tr>
</thead>
<tbody>
<tr>
<td>define1</td>
<td>SRCDATA</td>
<td>study1</td>
<td>Protocol abc</td>
<td>first study</td>
</tr>
</tbody>
</table>

### VIEWTABLE: Sdtmmeta.Source_tables (Source Table Metadata)

<table>
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<tr>
<th>SASref</th>
<th>Table</th>
<th>Label</th>
<th>Class</th>
<th>XMLPath</th>
<th>XmlTitle</th>
<th>Structure</th>
<th>Purpose</th>
<th>Keys</th>
</tr>
</thead>
<tbody>
<tr>
<td>SRCDATA</td>
<td>AE</td>
<td>Adverse Events</td>
<td>Events</td>
<td>../transport/ae.xpt</td>
<td>Adverse Events SAS transport file</td>
<td>One record per adverse event per subject</td>
<td>Tabulation</td>
<td>STUDYID USUBJID AEDECOD AESTDTCC</td>
</tr>
<tr>
<td>SRCDATA</td>
<td>CE</td>
<td>Clinical Events</td>
<td>Events</td>
<td>../transport/ce.xpt</td>
<td>Clinical Events SAS transport file</td>
<td>One record per event per subject</td>
<td>Tabulation</td>
<td>STUDYID USUBJID CETERM CESTDTCC</td>
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<td>SRCDATA</td>
<td>CM</td>
<td>Concomitant Medications</td>
<td>Interventions</td>
<td>../transport/cm.xpt</td>
<td>Concomitant Medications SAS transport file</td>
<td>One record per recorded medication occurrence or constant dosing interval per subject</td>
<td>Tabulation</td>
<td>STUDYID USUBJID CMTRT CMSTDTCC</td>
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### VIEWTABLE: Sdtmmeta.Source_columns (Source Column Metadata)

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<td>Severity/Intensity</td>
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<td>C</td>
<td>20</td>
<td>text</td>
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<td>18</td>
<td>C</td>
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<td>Exp</td>
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Value Level Metadata
**Value Level Metadata**

- Update the CRT-DDS SAS datasets to get Value level metadata

### Vital Signs Dataset (VS)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Label</th>
<th>Type</th>
<th>Controlled Terms or Format</th>
<th>Origin</th>
<th>Role</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDYID</td>
<td>Study Identifier</td>
<td>text</td>
<td></td>
<td>Identifier</td>
<td></td>
<td>Unique identifier for a study.</td>
</tr>
<tr>
<td>VSSPID</td>
<td>Sponsor-Denna Identifier</td>
<td>text</td>
<td></td>
<td>Identifier</td>
<td></td>
<td>Sponsor-Denna reference number. Perhaps pre-printed on the CRT as an explicit line identifier or defined in the sponsor's operational database.</td>
</tr>
<tr>
<td>VSTESTCD</td>
<td>Vital Signs Test Short Name</td>
<td>text</td>
<td>VSTESTCD</td>
<td>Topic</td>
<td></td>
<td>Short name of the measurement, test, or examination described in VTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in VSTESTCD cannot be longer than 8 characters, nor can it start with</td>
</tr>
</tbody>
</table>

| VSTESTCD   | DIABP                    | Diastolic Blood Pressure | integer | CRF Page 11 |
| VSTESTCD   | FRMSIZE                  | Frame Size              | text    | CRF Page 11 |
| VSTESTCD   | HRATE                    | Heart Rate              | integer | CRF Page 11 |
| VSTESTCD   | PULBP                    | Pulse Pressure          | integer | CRF Page 11 |
| VSTESTCD   | SYSBP                    | Systolic Blood Pressure | integer | CRF Page 11 |
## Value Level Metadata

### VIEWTABLE: sdmmtm.meta.Source.columns (Source Column Metadata)

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<th>table</th>
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<th>type</th>
<th>length</th>
<th>display</th>
<th>xtype</th>
<th>xml_code_list</th>
<th>core</th>
<th>origin</th>
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<td>Unique Subject Identifier</td>
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### VIEWTABLE: sdmmtm.meta.Source.values (Source Value Metadata)

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<th>xml_code_list</th>
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</table>
Adding Value Level Metadata
from source_values SAS data set
Value Level Metadata

- Update the CRT-DDS SAS datasets:
  » Value level metadata
Value Level Metadata

- Update the CRT-DDS SAS datasets to get Value level metadata
  - Manual process in 1.4
  - Automated in 1.5

ValueLists – contains id of value lists
ValueListItemRefs – contains id of each item in a value list
ItemValueListRefs – associates each value list item to a row in the ItemDefs dataset
ItemDefs – contains metadata for each id in ValueListItemRefs
SAS Clinical Standards Toolkit: resources

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

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)

CST 1.4 Value Level Metadata example code
SAS Clinical Standards Toolkit: resources

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

KNOWLEDGE BASE / FOCUS AREAS

FOCUS AREAS

• Base SAS
  • CDISC
    - Clinical Standards Toolkit
    - PROC CDISC
  • DATA Step
  • ODS
  • SAS98
  • Universal Printing
  • XML Engine
  • Preproduction
• Data Visualization
• Enterprise Management Integration
• Migration
• Scalability & Performance
• Statistics & Operations Research
• SAS AppDev Studio

Base SAS

SAS® Clinical Standards Toolkit

The SAS® Clinical Standards Toolkit 1.4 provides support of multiple CDISC standards, including SDTM (3.1.1 and 3.1.2), CRTDDS (reading and creating define xml files), ODM (reading and creating 1.3.0 xml files) and ADaM 2.1. This tool is the platform used by SAS to support Health and Life Sciences industry data model standards. SAS Clinical Standards Toolkit is under active development with multiple releases planned in its product roadmap.

The recent release of SAS Clinical Standards Toolkit 1.4 provides full support of the CDISC-ODM 1.3.0 standard (reading and creating ODM xml files), the CDISC ADaM 2.1 standard (ADSL, Basic Data Structure and Analysis Results Metadata templates, as well as version 1.1 of the ADaM validation checks), and a CDISC Controlled Terminology package that includes the cumulative set of terminology as posted to the NCI FTP site as of April 2011. This set of terminology is sufficient to support the CDISC-SDTM 3.1.2 and ADaM 2.1 standards.

SAS Clinical Standards Toolkit 1.4 is supported with SAS 9.3 on the following operating systems:

• Windows 32
• Windows x64
• Linux x64
• Solaris SPARC
• Solaris AMD
• HP-UX Itanium

The toolkit is a separately orderable component that is available at no additional charge to currently licensed SAS customers. Contact your SAS Account Representative concerning availability.

Ordering the Toolkit

SAS 9.3

SAS Clinical Standards Toolkit version 1.4 for SAS 9.3 must be ordered through normal channels. Contact your SAS representative to have SAS Clinical Standards Toolkit added to your existing SAS license(s) for no additional fee.
SAS Clinical Standards Toolkit: resources

SAS Clinical Standards Toolkit

SAS Clinical Standards Toolkit 1.4

- SAS Clinical Data Standards Toolkit 1.4: Installation Qualification [PDF] (1.77MB)
- SAS Clinical Standards Toolkit 1.4: Getting Started [PDF] (965KB)
- SAS Clinical Standards Toolkit 1.4: User's Guide [PDF] (14MB) [HTML]

SAS Clinical Standards Toolkit 1.3

- SAS Clinical Data Standards Toolkit 1.3: Installation Qualification [PDF] (791KB)
- SAS Clinical Standards Toolkit 1.3: User's Guide [PDF] (5.26MB) [HTML]

SAS Clinical Standards Toolkit 1.2

- SAS Clinical Standards Toolkit 1.2: Quick Start for SDTM Validation for SAS 9.2 and SAS 9.1.3 [PDF] (323KB)
- SAS Clinical Standards Toolkit in SAS 9.1.3: Installation Instructions [PDF] (490KB)
SAS Clinical Standards Toolkit: resources

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- 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)


- 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)


- 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)