

Define's New Style

A review of stylesheet updates

AMY GARRETT, Product Manager

August 21, 2019

4.1.4.5 Data Definition Files for SDTM, SEND, and ADaM

The data definition file describes the metadata of the submitted electronic datasets, and is considered arguably the most important part of the electronic dataset submission for regulatory review. This data definition specification for submitted datasets defines the metadata structures that should be used to describe the datasets, variables, possible values of variables when appropriate, and controlled terminologies and codes. An insufficiently documented data definition file is a common deficiency that reviewers have noted.

DEFINE.XML IMPORTANCE

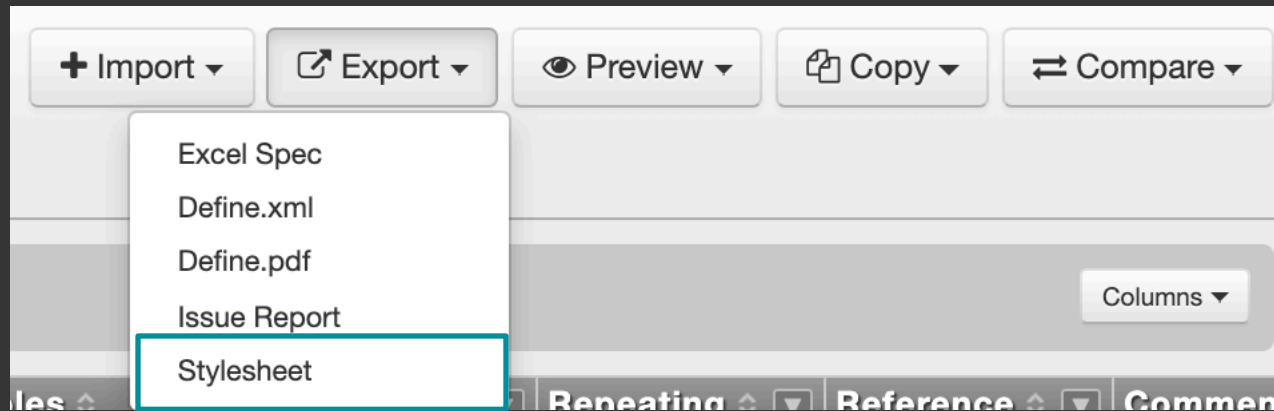
Define.xml is the most important part of your submission.

STYLESHEET UPDATES

A stylesheet transforms your define.xml into a human readable format.

Accessing the Stylesheet

- › Download latest from P21E Define Designer



- › Download from PhUSE:

<http://www.phusewiki.org/docs/WorkingGroups/XML/Define-XML%202.0%20Stylesheet%20Recommendations.zip>

A lot has changed

- › Published Nov 21st 2018
- › Last published January 16th 2015

```

<!-- ..... -->
<!-- File:      define2-0.xsl -->
<!-- Description: This stylesheet works with the Define-XML 2.0.x specification, including the Analysis -->
<!-- Results Metadata v1.0 extension. -->
<!-- Author:    Lex Jansen, CDISC Data Exchange Standards Team -->
<!-- -->
<!-- Changes: -->
<!-- 2018-11-21 - Code cleanup -->
<!-- 2018-10-24 - Added PublishingSet to Standard display in CodeLists (Draft Define-XML 2.1) -->
<!-- 2018-08-09 - Fixed issue when there is no ItemGroupDef/@def:ArchiveLocationID -->
<!-- 2018-07-24 - Change Derivation to Method -->
<!-- - Added tags for unresolved references -->
<!-- - Always use Name attribute in Datasets table and header row (instead of SASDatasetName) -->
<!-- - Show pointer for cursor for VLM hyperlinks and buttons to show they are clickable objects -->
<!-- - Fix bug to allow Supplemental variable keys to be mid key-order, not just at the end -->
<!-- - Also fixed this for AP domains that have SQ supplemental variables. -->
<!-- - Use Name rather than SASDatasetName for consistency. -->
<!-- 2018-04-20 - Removed def:Standard/IsDefault (Draft Define-XML 2.1) -->
<!-- - Added CodeList/def:IsNonStandard (Draft Define-XML 2.1) -->
<!-- 2018-03-01 - Made ARM table background consistent with other tables. -->
<!-- - Restored separation line in ARM summary listing. -->
<!-- - Added more vertical spacing between Expand All/Collapse All VLM buttons. -->
<!-- - Fixed bug where only one FormalExpression element was supported per MethodDef element. -->
<!-- - Changed LE and GE comparators to use Unicode &#x2264 and &#x2265. -->
<!-- - Made links from datasets in ARM consistent. Both will now go to the summary dataset table. -->
<!-- 2018-02-26 - Added version 2.1 comments. -->
<!-- - Improved Expand All/Collapse All VLM buttons rounded corners. -->
<!-- 2018-02-16 - Added Class/SubClass (Draft Define-XML 2.1) -->
<!-- 2018-02-13 - Improved Expand All/Collapse All VLM buttons. -->
<!-- 2018-01-30 - Change Expand All/Collapse All VLM to buttons. -->
<!-- 2018-01-25 - Give VLM rows the same background color as governing row. -->
<!-- - Some label updates. -->
<!-- 2017-12-27 - Add Condition column only when there is VLM. -->
<!-- - Collapse/expand VLM rows. -->
<!-- 2017-12-06 - Sort ItemRefs in VLM by OrderNumber. -->
<!-- 2017-11-20 - Further tweaking of VLM within dataset variable tables, including nested VLM for SuppQuals. -->
<!-- - Fixed collapsed study metadata display when an attribute is empty. -->
<!-- 2017-11-20 - Initial implementation of VLM within dataset variable tables (no nested VLM yet). -->
<!-- 2017-10-23 - Support for CodeListItem/Description and EnumeratedItem/Description (Draft Define-XML 2.1) -->
<!-- - Support for Associated Persons Supplemental Qualifiers. -->
<!-- 2017-08-28 - Small fixes: ISO8601 -> ISO 8601, No data -> No Data, NonStandard -> Non Standard. -->
<!-- 2017-08-02 - Removed display of OIDs from CodeList tables. -->
<!-- 2017-08-01 - Fixed display for named destination with '#20' (blank). -->
<!-- 2017-07-31 - Fixed link to XPT transport files (/ItemGroupDef/def:leaf) to open external. -->
<!-- - Removed link to related dataset from the bottom of the table. -->
<!-- - Improved breaks in composite WhereClause display. -->
<!-- - Added non-breaking space to codelist item display in variable table, which improves break. -->
<!-- - Fixed linking to items in WhereClause that do not belong to the current ItemGroup, which -->
<!-- will only work for items that are referenced in an ItemGroup and can uniquely be found. -->
<!-- 2017-07-23 - Improved display for VLM for SuppQuals. -->
<!-- 2017-07-21 - Added support for multiple destinations in a def:PDFPageRef/PageRefs attribute. -->

```

A lot has changed...

- Change log is at the top of the stylesheet

```

<!-- 2017-11-20 - Further tweaking of VLM within dataset variable tables, including nested VLM for SuppQuals.-->
<!-- - Fixed collapsed study metadata display when an attribute is empty. -->
<!-- 2017-11-20 - Initial implementation of VLM within dataset variable tables (no nested VLM yet). -->
<!-- 2017-10-23 - Support for CodeListItem/Description and EnumeratedItem/Description (Draft Define-XML 2.1) -->
<!-- - Support for Associated Persons Supplemental Qualifiers. -->
<!-- 2017-08-28 - Small fixes: ISO8601 -> ISO 8601, No data -> No Data, NonStandard -> Non Standard. -->
<!-- 2017-08-02 - Removed display of OIDs from CodeList tables. -->
<!-- 2017-08-01 - Fixed display for named destination with '#20' (blank). -->
<!-- 2017-07-31 - Fixed link to XPT transport files (/ItemGroupDef/def:leaf) to open external. -->
<!-- - Removed link to related dataset from the bottom of the table. -->
<!-- - Improved breaks in composite WhereClause display. -->
<!-- - Added non-breaking space to codelist item display in variable table, which improves break. -->
<!-- - Fixed linking to items in WhereClause that do not belong to the current ItemGroup, which -->
<!-- will only work for items that are referenced in an ItemGroup and can uniquely be found. -->
<!-- 2017-07-23 - Improved display for VLM for SuppQuals. -->
<!-- 2017-07-21 - Added support for multiple destinations in a def:PDFPageRef/PageRefs attribute. -->
<!-- 2017-07-17 - Added display of: -->
<!-- - ItemGroupDef/def:HasNoData, ItemRef/def:HasNoData (Draft Define-XML 2.1) -->
<!-- - Added display of ItemRef/@Role in variable tables and VLM tables, when defined. -->
<!-- - Completed display of document references. -->
<!-- 2017-07-07 - Display round brackets with multiple def:WhereClauseRefs. -->
<!-- 2017-06-19 - Consistency between SDS and ADaM. -->
<!-- 2017-06-05 - Changed displayCommentsTable parameter default to 0. -->
<!-- 2017-05-23 - Added display of key variables as defined in SUPPxx datasets. -->
<!-- 2017-05-19 - Added display of ODM/@Context. -->
<!-- - Added display of CodeListItem/@Rank and odm:EnumeratedItem/@Rank. -->
<!-- - Added display of keys when they are part of SuppQuals. -->
<!-- - Changed column label "Controlled Terms or Format" to "Controlled Terms or ISO Format" -->
<!-- - Changed Methods label to "Derivations" and ValueLists to "Value Level Metadata" -->
<!-- 2017-03-28 - Removed Key column from variable metadata table. -->
<!-- 2017-03-19 - SDTM/SEND/ADaM variable metadata tables now have the same columns and headers. -->
<!-- 2017-03-15 - Added Added link to MethodDef/FormalExpression from dataset/VLM table. -->
<!-- - Honoring leading blanks in methods. -->
<!-- - Honoring leading blanks in CodeListItem Decodes in the CodeLists table. -->
<!-- - Removed check for valid ItemGroupDef/@Purpose values. -->
<!-- 2017-02-16 - Added External CodeList comments display. -->
<!-- - The TableItemDefSDS template now displays DisplayFormat instead of Length when available. -->
<!-- 2017-01-10 - Fixed duplicate CRF title display. -->
<!-- 2016-12-07 - Fixed display of Origin Description when there is more than one. -->
<!-- 2016-11-15 - Switched Location and Documentation in dataset display. -->
<!-- 2016-10-31 - Changed Standard/StandardVersion display to StudyName. -->
<!-- 2016-08-25 - Removed duplicate Standard/StandardVersion display in Define-XML 2.1. -->
<!-- - Making dataset names clickable instead of labels for consistency. -->
<!-- - Variable name no longer links to VLM, but a separate superscript "VLM" link. -->
<!-- - In Analysis Results Details table, add link to dataset an analysis variable is coming from.-->
<!-- 2016-08-08 - Added external documents icon. -->
<!-- 2016-08-01 - Fixed external documents display in a new window for documents in TOC. -->
<!-- 2016-07-14 - Added Supplemental Documents container. -->
<!-- - Open external documents (pdf) in a new window. -->
<!-- 2016-07-05 - Added Page display to linkSinglePageHyperlink template. -->
<!-- 2016-06-21 - Improved ARM arm:Code display by wrapping really long lines. -->

```

...continued

> Change log is at the top of the stylesheet

```

<!-- 2016-07-05 - Added Page display to linkSinglePageHyperlink template. -->
<!-- 2016-06-21 - Improved ARM arm:Code display by wrapping really long lines. -->
<!-- 2016-06-09 - Added displayPrefix and displayLengthDFormatSD parameters. -->
<!-- - Honoring linebreaks in methods (also changed to indent="no"). -->
<!-- - Changed Standard/@Package to Standard/@PublishingSet (Draft Define-XML 2.1). -->
<!-- 2016-03-10 - Updated ItemDef display of: Length [Significant Digits] : Display Format. -->
<!-- 2016-03-09 - Added Comment and DocumentRef display (Drfat Define-XML 2.1) for MetaDataVersion and -->
<!-- CodeList. -->
<!-- - Added display of: -->
<!-- ItemGroupDef/def:StandardOID, ItemGroupDef/def:IsNonStandard, CodeList/def:StandardOID -->
<!-- - Added display of def:Origin/@Source (Draft Define-XML 2.1). -->
<!-- - Added Standard table (Draft Define-XML 2.1). -->
<!-- - Added def:PDFPageRef/@Title -->
<!-- - Changed the Method display to honor linebreaks. -->
<!-- 2016-03-02 - Added prefixes in 'Derivation / Comment' and 'Source / Derivation / Comment' columns. -->
<!-- - Added display of MethodDef/FormalExpression. -->
<!-- - Added display of CodeList/Description. -->
<!-- - Added display of def:Origin/Description and def:DocumentRef. -->
<!-- - Added display of ValueList/Description (Draft Define-XML 2.1). -->
<!-- - Added display of ExternalCodeList/ExternalCodeList/@ref. -->
<!-- 2016-02-11 - Improved Controlled Terms or Format display for CodeList Items and Enumerated Items. -->
<!-- The number of CodeList Items to display in the "Controlled Terms or Format" column is now -->
<!-- driven by the parameter nCodeListItemDisplay (default=5). -->
<!-- For external dictionaries the dictionary and version are displayed in the "Controlled -->
<!-- Terms or Format" column below the link. -->
<!-- 2016-02-08 - CRF Origin display no longer hardcoded as "CRF Page", but uses the real title. -->
<!-- - Display of "ISO 8601" in the "Controlled Terms or Format" column is now completely driven -->
<!-- by the DataType. -->
<!-- 2016-02-04 - Fixed issue with PDF pages that are invalid, for example 12A. -->
<!-- 2015-02-13 - Fixed issue where multiple documents would result in displaying the first document -->
<!-- multiple times in the Dataset and Value Level Metadata sections. -->
<!-- - For displaying the annotated CRF documents: -->
<!-- When there is no def:AnnotatedCRF element, loop over the def:leaf elements and see if -->
<!-- these are referenced from any ItemDef/def:Origin/def:DocumentRef elements. -->
<!-- - Added support for multiple def:Origin elements and multiple documents within a def:Origin. -->
<!-- - Links to Annotated CRFs in def:Origin is no longer taken from the def:AnnotatedCRF element -->
<!-- 2015-01-16 - Added Study metadata display -->
<!-- - Improved Analysis Parameter(s) display -->

```

...continued

> Change log is at the top of the stylesheet

Notable Changes

- › Sidebar
- › Value Level Metadata
- › Origin, Methods, and Comments
- › CT

2015 (old)

SDTM-IG 3.1.2

- Annotated Case Report Form
- Reviewers Guide
- Complex Algorithms
- ▶ Tabulation Datasets
- ▶ Value Level Metadata
- ▶ Controlled Terminology
- ▶ Computational Algorithms
- ▶ Comments

2018 (new)

CDISC01

- Annotated Case Report Form 
- ▼ Supplemental Documents
 - Reviewers Guide 
 - Complex Algorithms 
- ▶ Datasets
- ▶ Controlled Terminology
- ▶ Methods

Expand all VLM

Collapse all VLM

Sidebar – SDTM

- › Header is StudyName (not StandardName and StandardVersion)
- › Dedicated section for Supplemental Documents
- › Comments removed
- › VLM section removed, replaced with Expand/Collapse VLM buttons

2015 (old)

ADaM-IG 1.0

- Analysis Data Reviewer's Guide
- ▶ Analysis Results Metadata
- ▶ Analysis Datasets
- ▶ Parameter Value Level Metadata
- ▶ Controlled Terminology
- ▶ Analysis Derivations
- ▶ Comments

2018 (new)

CDISC-Sample

- ▼ Supplemental Documents
 - Analysis Data Reviewer's Guide
- ▶ Analysis Results Metadata
- ▶ Datasets
- ▶ Controlled Terminology
- ▶ Methods

Expand all VLM

Collapse all VLM

Sidebar - ADaM

- › Header is StudyName (not StandardName and StandardVersion)
- › Dedicated section for Supplemental Documents
- › Comments removed
- › VLM section removed, replaced with Expand/Collapse VLM buttons

Value Level Metadata - EG [EGSTRESC]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
EGSTRESC	EGTESTCD = "QTcB" (QTcB - Bazett's Correction Formula)	float	5.1		Derived	QTcB = QT interval / square root of (60 / heart rate). For the complete algorithm see the referenced external document. Complex Algorithms
EGSTRESC	EGTESTCD = "QTcF" (QTcF - Fridericia's Correction Formula)	float	5.1		Derived	QTcF = QT interval / cubic root of (60 / heart rate). For the complete algorithm see the referenced external document. Complex Algorithms

Value Level Metadata – OLD

- › Dedicated section for VLM

Related Supplemental Qualifiers Dataset: SUPPEG (Supplemental Qualifiers for EG)						
Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
EGSTRESC VLM		Character Result/Finding in Std Format	text	15		Derived Data collected in non-standard units is converted using standard conversion factors to standard units.
	EGTESTCD = "QTcB" (QTcB - Bazett's Correction Formula)	QTcB - Bazett's Correction Formula	float	5.1		Derived QTcB = QT interval / square root of (60 / heart rate). For the complete algorithm see the referenced external document. Complex Algorithms [EG]
	EGTESTCD = "QTcF" (QTcF - Fridericia's Correction Formula)	QTcF - Fridericia's Correction Formula	float	5.1		Derived QTcF = QT interval / cubic root of (60 / heart rate). For the complete algorithm see the referenced external document. Complex Algorithms [EG]

Value Level Metadata - NEW

- > When Expanded, VLM displayed under the variable

PE (Physical Examination) - FINDINGS

Location: [pe.xpt](#)

Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID		Study Identifier	text	7		Protocol
DOMAIN		Domain Abbreviation	text	2	Domain Abbreviation (PE) • "PE" = "Physical Exam"	Assigned
USUBJID		Unique Subject Identifier	text	14		Derived Concatenation of STUDYID and SUBJID Formal Expression
PESEQ		Sequence Number	integer	2		Derived Sequential number identifying records within each USUBJID in the domain.
PETESTCD		Body System Examined Short Name	text	4	PE Test Codes [9 Terms]	Assigned
PETEST		Body System Examined	text	29	PE Tests [9 Terms]	CRF Annotated Case Report Form [10]
PEORRES VLM		Verbatim Examination Finding	text	36		CRF Annotated Case Report Form [10]
PESTRESC		Character Result/Finding in Std Format	text	26		Derived PESTRESC = PEORRES
VISITNUM		Visit Number	integer	2		Assigned Assigned from the TV domain based on the VISIT

Value Level Metadata - NEW

- › When Collapsed, Where Condition column looks empty.

Concomitant Medications (CM) [Location: [cm.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	7		Protocol	
DOMAIN	Domain Abbreviation		text	2	["CM" = "Concomitant Meds"] < Domain Abbreviation (CM) >	Assigned	
USUBJID	Unique Subject Identifier	2	text	14		Derived	Concatenation of STUDYID and SUBJID
CMSEQ	Sequence Number		integer	2		Derived	Sequential number identifying records within each USUBJID in the domain.
CMTRT	Reported Name of Drug, Med, or Therapy	6	text	23		CRF Pages 9 22	
CMMODIFY	Modified Reported Name		text	23		Assigned	

Origin, Method & Comment - OLD

- › One column for Origin
- › Separate column for Derivation/Comment

CM (Concomitant Medications) - INTERVENTIONSLocation: [cm.xpt](#)

Related Supplemental Qualifiers Dataset: SUPPCM (Supplemental Qualifiers for CM)					
Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	7		Protocol
DOMAIN	Domain Abbreviation	text	2	Domain Abbreviation (CM) • "CM" = "Concomitant Meds"	Assigned
USUBJID	Unique Subject Identifier	text	14		Derived Concatenation of STUDYID and SUBJID Formal Expression
CMSEQ	Sequence Number	integer	2		Derived Sequential number identifying records within each USUBJID in the domain.
CMTRT	Reported Name of Drug, Med, or Therapy	text	23		CRF Annotated Case Report Form [9 22]
CMMODIFY	Modified Reported Name	text	23		Assigned

Origin, Method & Comment - NEW

- > Combined column for Origin/Derivation/Comments

Variable	Label	Key	Type	Length	Controlled Terms or Format
STUDYID	Study Identifier	1	text	7	
DOMAIN	Domain Abbreviation		text	2	["DS" = "Disposition"] < Domain Abbreviation (DS) >
USUBJID	Unique Subject Identifier	2	text	14	
DSSEQ	Sequence Number		integer	1	
DSTERM	Reported Term for the Disposition Event		text	34	Reported Term for the Disposition Record
DSDECOD	Standardized Disposition Term	6	text	21	Completion/Reason for Non-Completion
DSCAT	Category for Disposition Event	5	text	18	["DISPOSITION EVENT" = "Disposition Event", "PROTOCOL MILESTONE" = "Protocol Milestone"] < Category for Disposition Event >
EPOCH	Epoch		text	9	["SCREEN", "TREATMENT"] < Epoch >

Controlled Terms or Format - OLD

- > Code and Decode values provided in brackets
- > Hyperlinks to codelists

Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format
STUDYID	Study Identifier	text	7	
DOMAIN	Domain Abbreviation	text	2	Domain Abbreviation (DS) • "DS" = "Disposition"
USUBJID	Unique Subject Identifier	text	14	
DSSEQ	Sequence Number	integer	1	
DSTERM	Reported Term for the Disposition Event	text	34	Reported Term for the Disposition Record [11 Terms]
DSDECOD	Standardized Disposition Term	text	21	Completion/Reason for Non-Completion [10 Terms]
DSCAT	Category for Disposition Event	text	18	Category for Disposition Event • "DISPOSITION EVENT" = "Disposition Event" • "PROTOCOL MILESTONE" = "Protocol Milestone"
EPOCH	Epoch	text	9	Epoch • "SCREEN" • "TREATMENT"

Controlled Terms or Format - NEW

- › Code and Decode values provided as bullet points
- › Hyperlinks to codelists include number of terms

Thank You!

Amy Garrett

Product Manager, Pinnacle 21