

Dataset-XML - A New CDISC Standard for Data Exchange

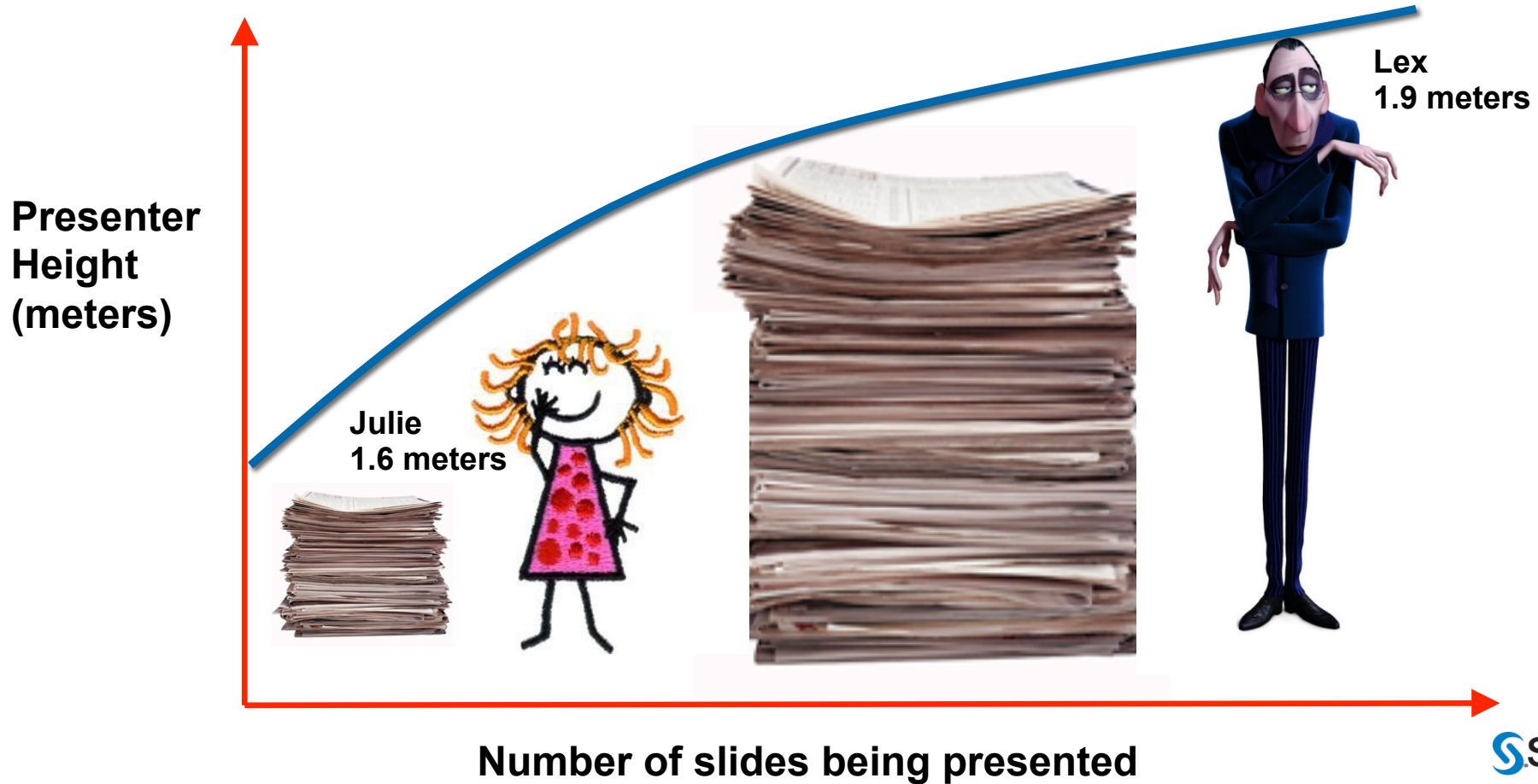


Julie Maddox and Lex Jansen
SAS Institute



PhUSE Annual Conference
October 2015
Vienna, Austria

PRESENTER HEIGHT VS AMOUNT OF PRESENTATION CONTENT



What is Dataset-XML

A New CDISC Standard for Data Exchange

- Alternative to SAS Version 5 Transport (**XPT**) format for data sets
- Based on **CDISC ODM**
- Capable of representing SDTM, SEND, ADaM or legacy **tabular** data set structures
- Aligned with **Define-XML** metadata
- Capability to support CDISC data submissions to the FDA
- Easy to transform to a data set for analysis

What is Dataset-XML

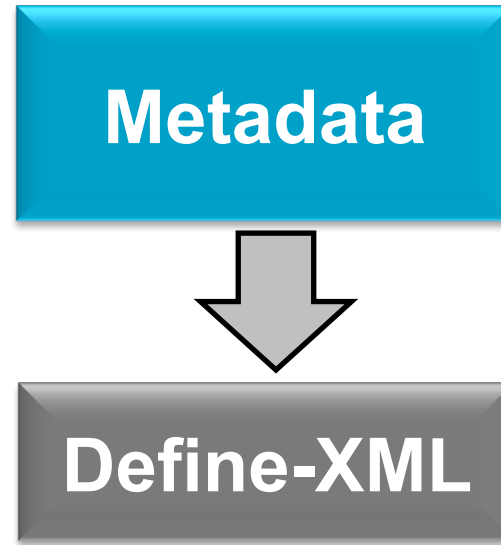
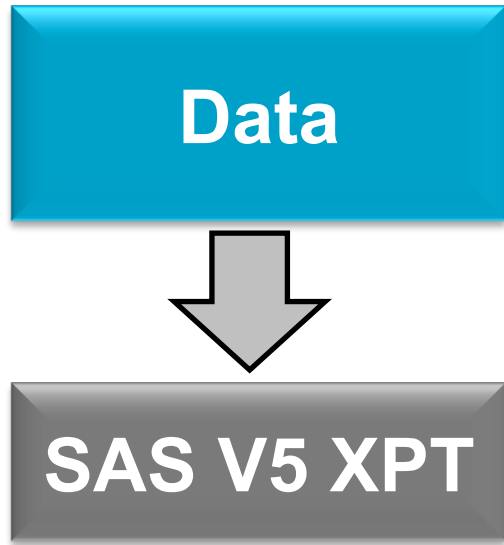
Benefits

- Open, non-proprietary standard without the field width or data set and variable naming restrictions of SAS V5 Transport files
- Harmonized with BRIDG, CDISC Controlled Terminology
- Data elements include references to metadata in Define-XML
- Straightforward implementation starting from tabular data in SAS
- Supports FDA goal of encouraging open source reviewer tool development
- Facilitates Validation since both data and metadata share underlying technology
- Enables re-thinking some of the length restrictions in standards

What is Dataset-XML

Data and Metadata

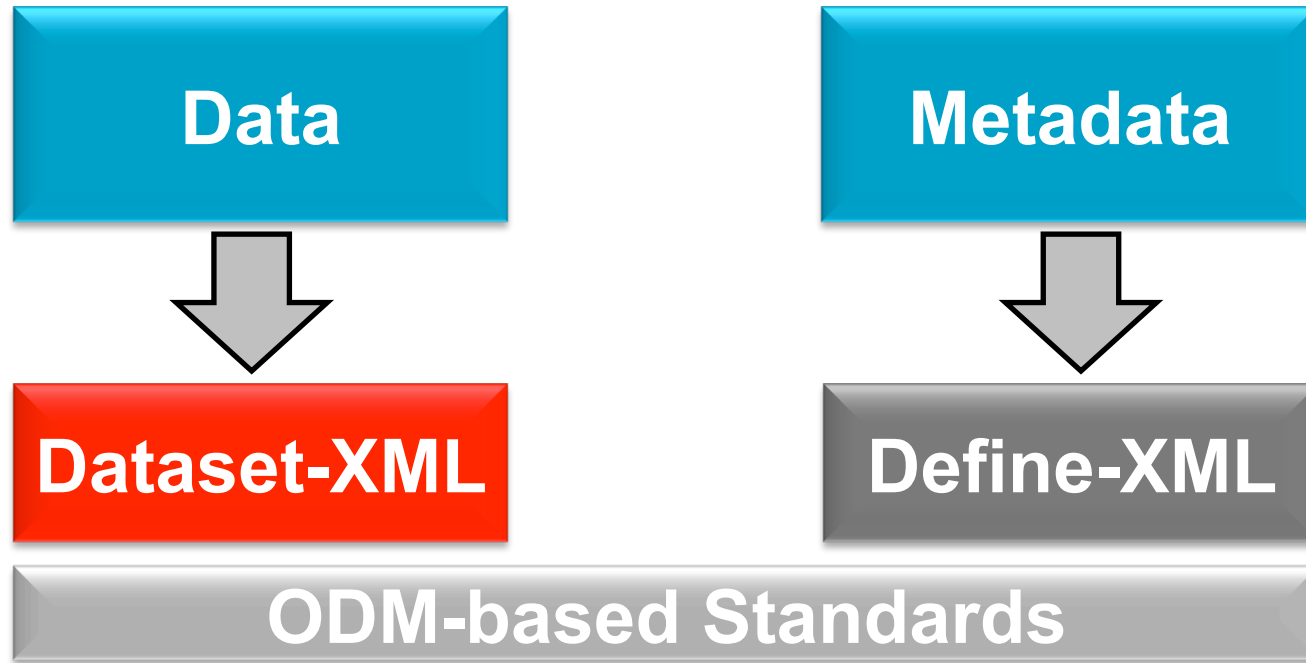
- Data and Metadata in Submissions Today



What is Dataset-XML

Data and Metadata

- Data and Metadata in Submissions Tomorrow



What is Dataset-XML

Data Transport

Today

 ae.xpt	SAS Xport Transport File
 blankcrf.pdf	Adobe Acrobat Document
 cm.xpt	SAS Xport Transport File
 complexalgorithms.pdf	Adobe Acrobat Document
 da.xpt	SAS Xport Transport File
 define.xml	XML Document
 define2-0-0.xsl	XSLT Stylesheet
 dm.xpt	SAS Xport Transport File
 ds.xpt	SAS Xport Transport File
 eg.xpt	SAS Xport Transport File
 ex.xpt	SAS Xport Transport File
 ie.xpt	SAS Xport Transport File
 lb.xpt	SAS Xport Transport File
 mh.xpt	SAS Xport Transport File
 pe.xpt	SAS Xport Transport File

```
<def:leaf ID="LF.AE" xlink:href="ae.xpt">  
  <def:title>ae.xpt</def:title>  
</def:leaf>
```

Tomorrow

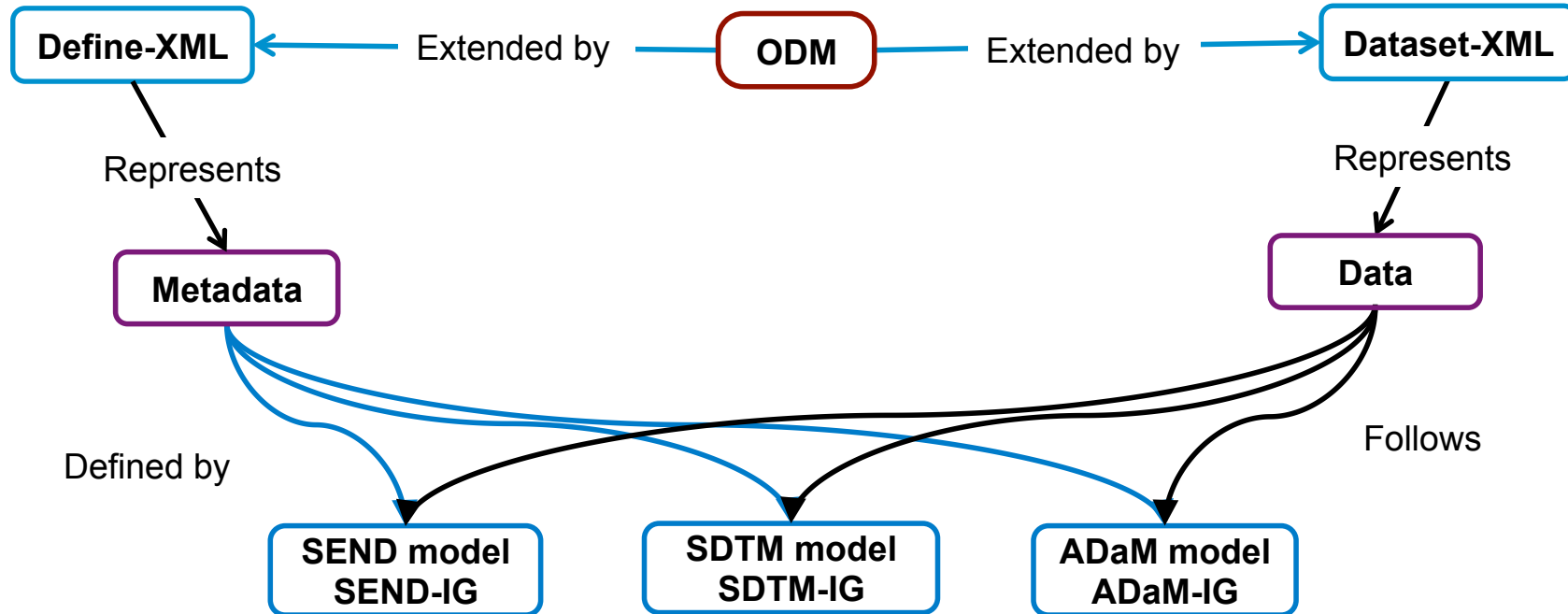
 ae.xml	XML Document
 blankcrf.pdf	Adobe Acrobat Document
 cm.xml	XML Document
 complexalgorithms.pdf	Adobe Acrobat Document
 da.xml	XML Document
 define.xml	XML Document
 define2-0-0.xsl	XSLT Stylesheet
 dm.xml	XML Document
 ds.xml	XML Document
 eg.xml	XML Document
 ex.xml	XML Document
 ie.xml	XML Document
 lb.xml	XML Document
 mh.xml	XML Document
 pe.xml	XML Document

```
<def:leaf ID="LF.AE" xlink:href="ae.xml">  
  <def:title>ae.xml</def:title>  
</def:leaf>
```

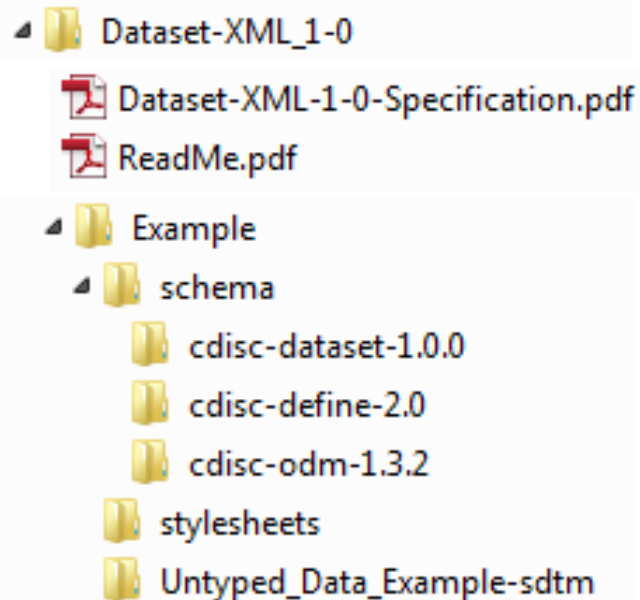
What is Dataset-XML

Data and Metadata

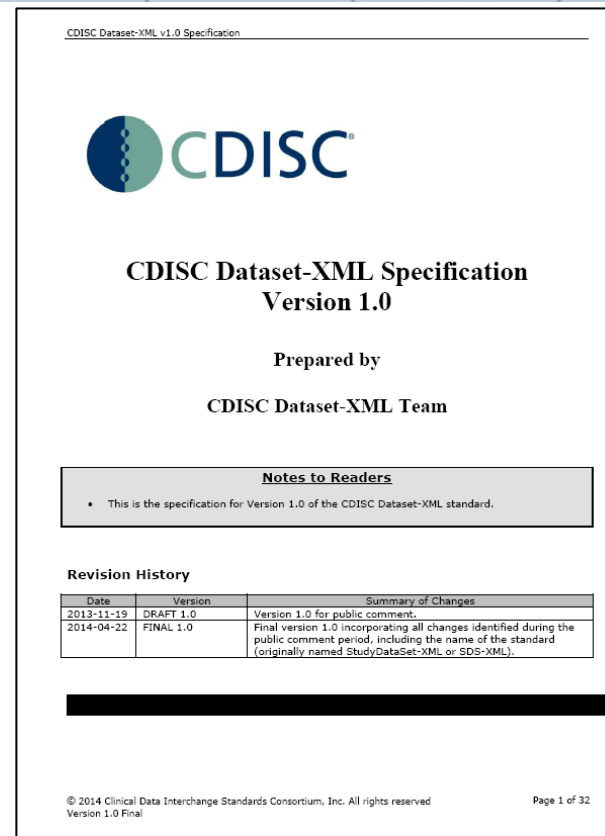
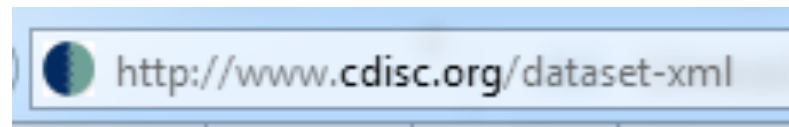
Relationship of Dataset-XML to other CDISC Standards



What is Dataset-XML Status



Final specification for version 1.0 released in April 2014



Date	Version	Summary of Changes
2013-11-19	DRAFT 1.0	Version 1.0 for public comment.
2014-04-22	FINAL 1.0	Final version 1.0 incorporating all changes identified during the public comment period, including the name of the standard (originally named StudyDataSet-XML or SDS-XML).

What is Dataset-XML

Status - Tools

<http://wiki.cdisc.org/display/PUB/CDISC+Dataset-XML+Resources>

Dataset-XML Tool Summary

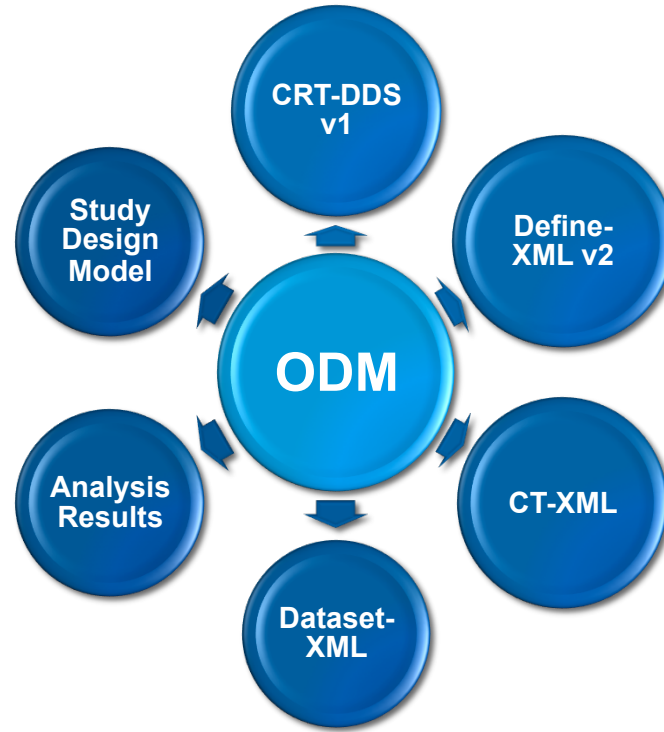
Name	Description
XPT2DatasetXML	- Transforms XPT datasets into Dataset-XML datasets - Freely available
Smart Dataset-XML Viewer	- Similar to the SAS Viewer, but with additional functionality - Supports working with Define-XML + Dataset-XML files - Supports SDTM, SEND, and ADaM data - Basic validation - Open source
EZ Convert	- Converts Dataset-XML files into SAS datasets - Supports Define-XML Version 1 or Version 2 - Open Source
SAS Clinical Standards Toolkit	- Dataset-XML support (writing/reading/validation) will be part of the next release of SAS® Clinical Standards Toolkit. Updated information will be published at the SAS web site. - Support for Dataset-XML is available as a pre-production package that contains SAS macros, XML schema files, sample data, and sample programs to support the following functionality: - 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 - These macros are standalone and do not require SAS® Clinical Standards Toolkit.
OpenCDISC v1.5	OpenCDISC v1.5 works with Dataset-XML files and Define-XML v2.0
R4CDISC	R4CDISC package includes functions for reading Dataset-XML and Define-XML files.

Dataset-XML and ODM



ODM EXTENSIONS

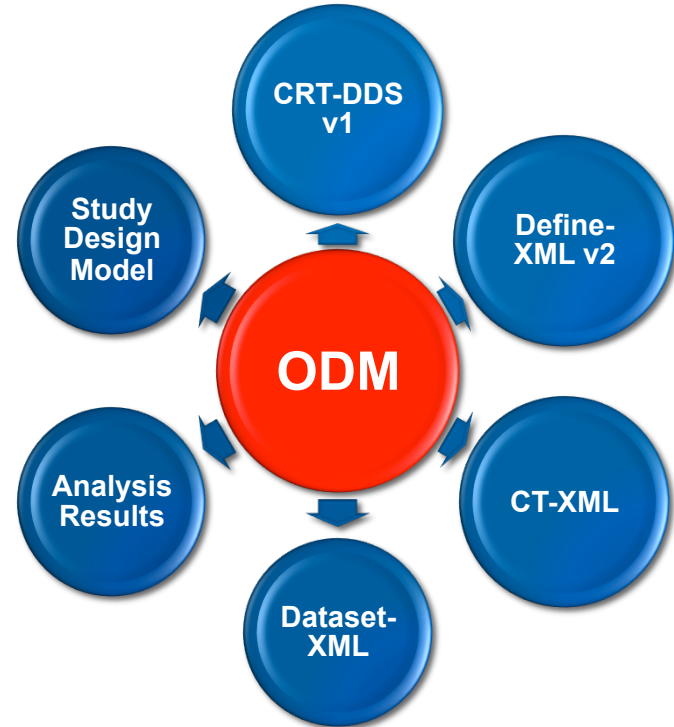
Represents an entire clinical study



ODM EXTENSIONS

Represents an entire clinical study

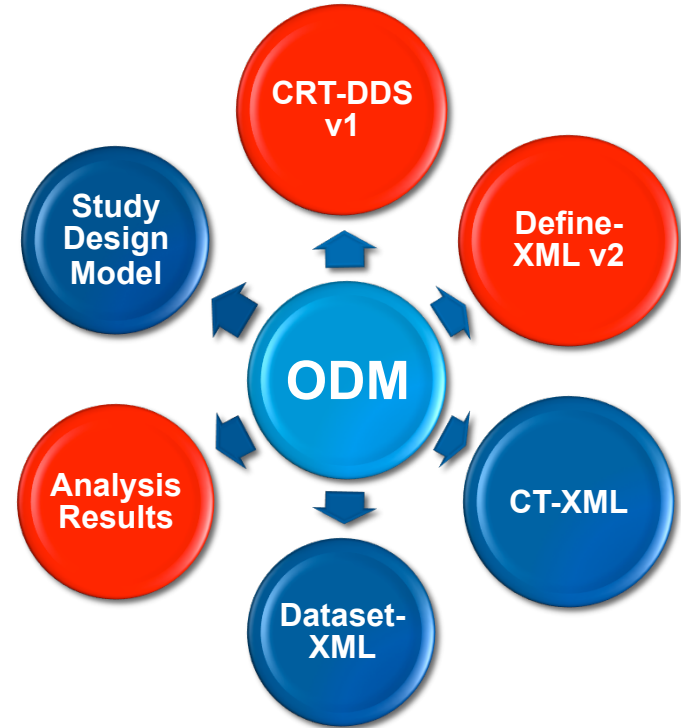
- **Vendor neutral** XML Schema for exchange and archive of Clinical Trials metadata and data: snapshots, updates, archives
- Supports **Part 11 compliance** and FDA Guidance on Computerized Systems
- Includes vendor **extension** capability
- Human and machine readable



ODM EXTENSIONS

Represents an entire clinical study

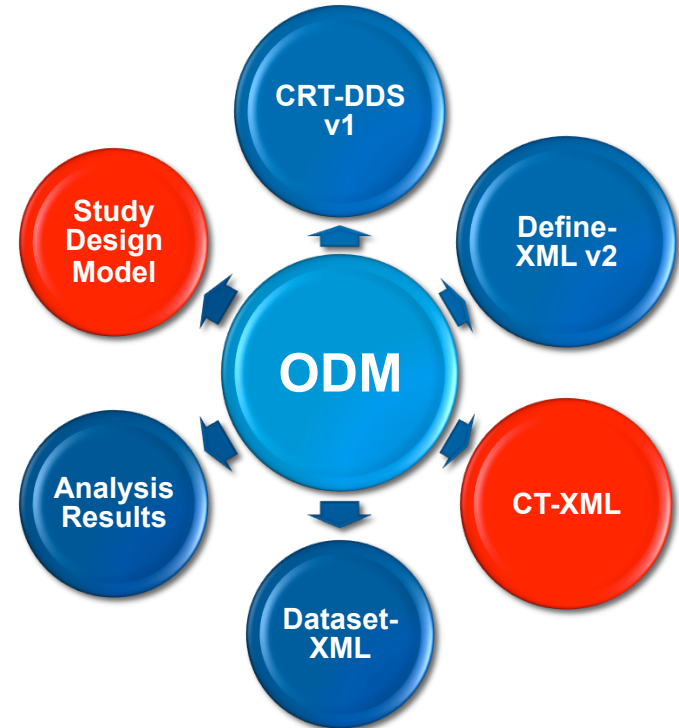
- Submission metadata – CRT-DDS, Define.xml
- Analysis Results metadata – extensions to Define.xml



ODM EXTENSIONS

Represents an entire clinical study

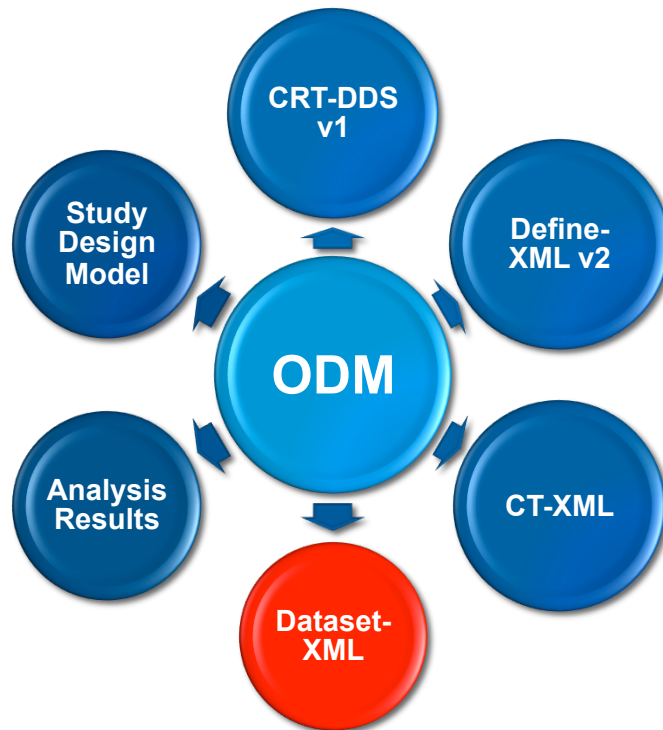
- SDM-XML represents BRIDG protocol/study design model (structure, workflow, timing)
- CT-XML delivers NCI-EVS controlled terminology



ODM EXTENSIONS

Represents an entire clinical study

- Study Subject data - Dataset-XML
- SDTM, SEND, ADaM , Legacy tabular data



Dataset-XML and ODM

Hierarchical metadata structure

- ODM file hierarchy for clinical data

<ODM>

<ClinicalData>

<SubjectData>

<StudyEventData>

<FormData>

<ItemGroupData>

<ItemData>

- Simplified Dataset-XML hierarchy

<ODM>

<ClinicalData>

<ItemGroupData>

<ItemData>

Dataset-XML and ODM

New Dataset-XML attributes

- Dataset-XML Version
/ODM/@data:DatasetXMLVersion
- Unique sequence number for each ItemGroupData
/ODM/ClinicalData/ItemGroupData/@data:ItemGroupDataSeq

```
<ODM
  xmlns="http://www.cdisc.org/ns/odm/v1.3"
  xmlns:xlink="http://www.w3.org/1999/xlink"
  xmlns:data="http://www.cdisc.org/ns/Dataset-XML/v1.0"
  FileType="Snapshot"
  ODMVersion="1.3.2"
  data:DatasetXMLVersion="1.0.0"
  FileOID="www.cdisc.org.Studydisc01-Define-XML_2.0.0(IG.AE)"
  PriorFileOID="www.cdisc.org.Studydisc01-Define-XML_2.0.0"
  Originator="CDISC Dataset-XML Team"
  CreationDateTime="2014-04-01T09:31:03">
  <ClinicalData
    StudyOID="cdisc01"
    MetadataVersionOID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2">
    <!-- Dataset (AE) -->
    <ItemGroupData ItemGroupOID="IG.AE" data:ItemGroupDataSeq="1">
```

Dataset-XML and ODM – Unique Object Identifiers

- In ODM, there are many instances where one object needs to **reference** another -- both **within** the same file and **across** files within a series of ODM documents
- To accomplish this, the target element is given a **unique identifier, OID**
- All elements that need to reference that target element just use its OID
- The values used for OIDs can follow any naming convention, or even can be randomly generated (e.g. IT.AE.AETERM , bc3e3f8e-62aa-4be4-879b-f5eb747e0d9e)
- The **only allowed use** of OIDs is to define an unambiguous link between a definition of an object and references to it

Dataset-XML and ODM– Unique Object Identifiers

```
<ClinicalData
  StudyOID="cdisc01"
  MetadataVersionOID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2">
  <!-- Dataset (AE) -->
  <ItemGroupData ItemGroupOID="IG.AE" data:ItemGroupDataSeq="1">
    <ItemData ItemOID="IT.STUDYID" Value="CDISC01"/>
    <ItemData ItemOID="IT.AE.DOMAIN" Value="AE"/>
    <ItemData ItemOID="IT.USUBJID" Value="CDISC01.100008"/>
    <ItemData ItemOID="IT.AE.AESEQ" Value="1"/>
    <ItemData ItemOID="IT.AE.AESPID" Value="1"/>
    <ItemData ItemOID="IT.AE.AETERM" Value="AGITATED"/>
  </ItemGroupData>
</ClinicalData>
```

Dataset-XML

```
<ItemGroupDef OID="IG.AE" Domain="AE" Name="AE"
  Repeating="Yes" IsReferenceData="No"
  SASDatasetName="AE" Purpose="Tabulation"
  def:Structure="One record per adverse event per subject"
  def:Class="EVENTS" def:ArchiveLocationID="LF.AE">
  <Description>
    <TranslatedText xml:lang="en">Adverse Events</TranslatedText>
  </Description>
  <ItemRef ItemOID="IT.STUDYID" OrderNumber="1" Mandatory="Yes" Key="Yes"/>
  <ItemRef ItemOID="IT.AE.DOMAIN" OrderNumber="2" Mandatory="Yes" Key="Yes"/>
  <ItemRef ItemOID="IT.USUBJID" OrderNumber="3" Mandatory="Yes" Key="Yes"/>
  <ItemRef ItemOID="IT.AE.AESEQ" OrderNumber="4" Mandatory="Yes" Key="Yes"/>
  <ItemRef ItemOID="IT.AE.AESPID" OrderNumber="5" Mandatory="No" Key="No"/>
  <ItemRef ItemOID="IT.AE.AETERM" OrderNumber="6" Mandatory="Yes" Key="Yes"/>
</ItemGroupDef>
```

```
<ItemDef OID="IT.AE.AETERM" Name="AETERM" DataType="text" Length="25" SASFieldName="AETERM">
  <Description>
    <TranslatedText xml:lang="en">Reported Term for the Adverse Event</TranslatedText>
  </Description>
  ...
</ItemDef>
```

Define.xml

Dataset-XML and Define-XML



Dataset-XML and Define-XML (data and metadata)

Data

VIEWTABLE: Sdtmdata.Ae (Adverse Events)

	STUDYID	DOMAIN	USUBJID	AESEQ	AESPID	AETERM	AEMODIFY	AEDECOD	AEBODSYS
1	CDISC01	AE	CDISC01.100008	1	1	AGITATED	AGITATION	Agitation	Psychiatric disorders
2	CDISC01	AE	CDISC01.100008	2	2	ANXIETY		Anxiety	Psychiatric disorders
3	CDISC01	AE	CDISC01.100008	3	3	DECREASED APPETITE		Decreased appetite	Metabolism and nutritior
4	CDISC01	AE	CDISC01.100014	1	1	DIARRHEA		Dianhoea	Gastrointestinal disorder
5	CDISC01	AE	CDISC01.100014	2	2	HEMORRHOID			
6	CDISC01	AE	CDISC01.100014	3	3	HEADACHE			
7	CDISC01	AE	CDISC01.100014	4	4	VOMIT			
8	CDISC01	AE	CDISC01.100014	5	5	VOMIT			
9	CDISC01	AE	CDISC01.200001	1	1	ANXIETY			
10	CDISC01	AE	CDISC01.200001	2	5	LEFT KNEE PAIN			

Metadata

Variables in Creation Order				
#	Variable	Type	Len	Label
1	STUDYID	Char	40	Study Identifier
2	DOMAIN	Char	8	Domain Abbreviation
3	USUBJID	Char	40	Unique Subject Identifier
4	AESEQ	Num	8	Sequence Number
5	AEGRPID	Char	40	Group ID
6	AEREFID	Char	40	Reference ID
7	AESPID	Char	40	Sponsor-Defined Identifier
8	AETERM	Char	200	Reported Term for the Adverse Event

Dataset-XML and Define-XML

Dataset-XML

```
<ODM
  xmlns="http://www.cdisc.org/ns/odm/v1.3"
  xmlns:data="http://www.cdisc.org/ns/Dataset-XML/v1.0"
  FileType="Snapshot"
  ODMVersion="1.3.2"
  data:DatasetXMLVersion="1.0.0"
  FileOID="cdisc01.AE"
  PriorFileOID="www.cdisc.org.Studycdisc01-Define-XML_2.0.0"
  CreationDateTime="2014-04-01T09:31:03">
  <ClinicalData StudyOID="cdisc01">
    <MetaDataVersionOID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2">
      <ItemGroupData ItemGroupOID="IG.AE"
        data:ItemGroupDataSeq="1">
        <ItemData ItemOID="IT.STUDYID" Value="CDISC01"/>
        <ItemData ItemOID="IT.AE.DOMAIN" Value="AE"/>
```

```
<ODM
  xmlns="http://www.cdisc.org/ns/odm/v1.3"
  xmlns:xlink="http://www.w3.org/1999/xlink"
  xmlns:def="http://www.cdisc.org/ns/def/v2.0"
  ODMVersion="1.3.2"
  FileOID="www.cdisc.org.Studycdisc01-Define-XML_2.0.0"
  FileType="Snapshot"
  CreationDateTime="2013-11-09T22:11:15">
  <Study OID="cdisc01">
    <GlobalVariables>
      <StudyName>CDISC01</StudyName>
      <StudyDescription>CDISC Test Study</StudyDescription>
      <ProtocolName>CDISC01</ProtocolName>
    </GlobalVariables>
    <MetaDataVersion
      OID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2"
      Name="Study CDISC01, Data Definitions"
      Description="Study CDISC01, Data Definitions"
      def:DefineVersion="2.0.0"
      def:StandardName="SDTM-IG"
      def:StandardVersion="3.1.2">
```

Define-XML

Dataset-XML and Define-XML (data)

VIEWTABLE: Edit data: Ae (Adverse Events)

```

- <ClinicalData MetaDataVersionOID="MDV.CDISC01" StudyOID="cdisc01">
  <!-- Dataset (AE) -->
  - <ItemGroupData data:ItemGroupDataSeq="1" ItemGroupOID="IG.AE">
    <ItemData Value="CDISC01" ItemOID="IT.STUDYID"/>
    <ItemData Value="AE" ItemOID="IT.AE.DOMAIN"/>
    <ItemData Value="1" ItemOID="IT.AE.AESPID"/>
    <ItemData Value="AGITATED" ItemOID="IT.AE.AETERM"/>
    <ItemData Value="AGITATION" ItemOID="IT.AE.AEMODIFY"/>
    <ItemData Value="Agitation" ItemOID="IT.AE.AEDECOD"/>
    <ItemData Value="Psychiatric disorders" ItemOID="IT.AE.AEBODSYS"/>
    <ItemData Value="MILD" ItemOID="IT.AE.AESEV"/>
    <ItemData Value="N" ItemOID="IT.AE.AESER"/>
    <ItemData Value="DOSE NOT CHANGED" ItemOID="IT.AE.AEACN"/>
    <ItemData Value="POSSIBLY RELATED" ItemOID="IT.AE.AEREL"/>
    <ItemData Value="2003-05" ItemOID="IT.AE.AESTDTC"/>
    <ItemData Value="3" ItemOID="IT.AE.AESTDY"/>
    <ItemData Value="AFTER" ItemOID="IT.AE.AEENRF"/>
  </ItemGroupData>
  
```

Row Number

Missing or Null, no corresponding ItemData element

AESPID	AETERM	AEMODIFY	AEDECOD	AEBODSYS	AEENDTC
1 1	AGITATED	AGITATION	Agitation	Psychiatric disorders	

cc

Dataset-XML and Define-XML (metadata)

Dataset-XML

```
- <ClinicalData MetaDataVersionOID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2"
StudyOID="cdisc01">
  <!-- Dataset (AE) -->
  - <ItemGroupData data:ItemGroupDataSeq="1" ItemGroupOID="IG.AE">
    <ItemData Value="CDISC01" ItemOID="IT.STUDYID"/>
    <ItemData Value="AE" ItemOID="IT.AE.DOMAIN"/>
    <ItemData Value="CDISC01.100008" ItemOID="IT.USUBJID"/>
    <ItemData Value="1" ItemOID="IT.AE.AESEQ"/>
    <ItemData Value="1" ItemOID="IT.AE.AESPID"/>
    <ItemData Value="AGITATED" ItemOID="IT.AE.AETERM"/>
    <ItemData Value="AGITATION" ItemOID="IT.AE.AEMODIFY"/>
    <ItemData Value="Agitation" ItemOID="IT.AE.AEDECOD"/>
    <ItemData Value="Psychiatric disorders" ItemOID="IT.AE.AEBODSYS"/>
    <ItemData Value="MILD" ItemOID="IT.AE.AESEV"/>
    <ItemData Value="N" ItemOID="IT.AE.AESER"/>
    <ItemData Value="DOSE NOT CHANGED" ItemOID="IT.AE.AEACN"/>
    <ItemData Value="POSSIBLY RELATED" ItemOID="IT.AE.AEREL"/>
    <ItemData Value="2003-05" ItemOID="IT.AE.AESTDTC"/>
    <ItemData Value="3" ItemOID="IT.AE.AESTDY"/>
    <ItemData Value="AFTER" ItemOID="IT.AE.AEENRF"/>
  </ItemGroupData>
```

OIDs

Metadata

```
<ItemRef ItemOID="IG.AE" Domain="AE" Name="AE"
Repeating="Yes" IsReferenceData="No"
SASDatasetName="AE" Purpose="Tabulation"
def:Structure="One record per adverse event per subject"
def:Class="FVE" S="def:LocationID="LF.AE">
  <Description>
    <TranslatedText>Adverse Events</TranslatedText>
  </Description>
  <ItemRef ItemOID="IT.STUDYID" OrderNumber="1" Mandatory="Yes" Key="Yes"/>
  <ItemRef ItemOID="IT.AE.DOMAIN" OrderNumber="2" Mandatory="Yes"/>
  <ItemRef ItemOID="IT.USUBJID" OrderNumber="3" Mandatory="Yes" Key="Yes"/>
  <ItemRef ItemOID="IT.AE.AESEQ" OrderNumber="4" Mandatory="Yes" Me="Yes"/>
  <ItemRef ItemOID="IT.AE.AESPID" OrderNumber="5" Mandatory="No"/>
  <ItemRef ItemOID="IT.AE.AETERM" OrderNumber="6" Mandatory="Yes"/>
```

```
<ItemDef OID="IT.AE.AETERM" Name="AETERM" DataType="text" Length="25" SASFieldName="AETERM">
  <Description>
    <TranslatedText xml:lang="en">Reported Term for the Adverse Event</TranslatedText>
  </Description>
  ...
</ItemDef>
```

Define.xml

SAS Tools for Dataset-XML



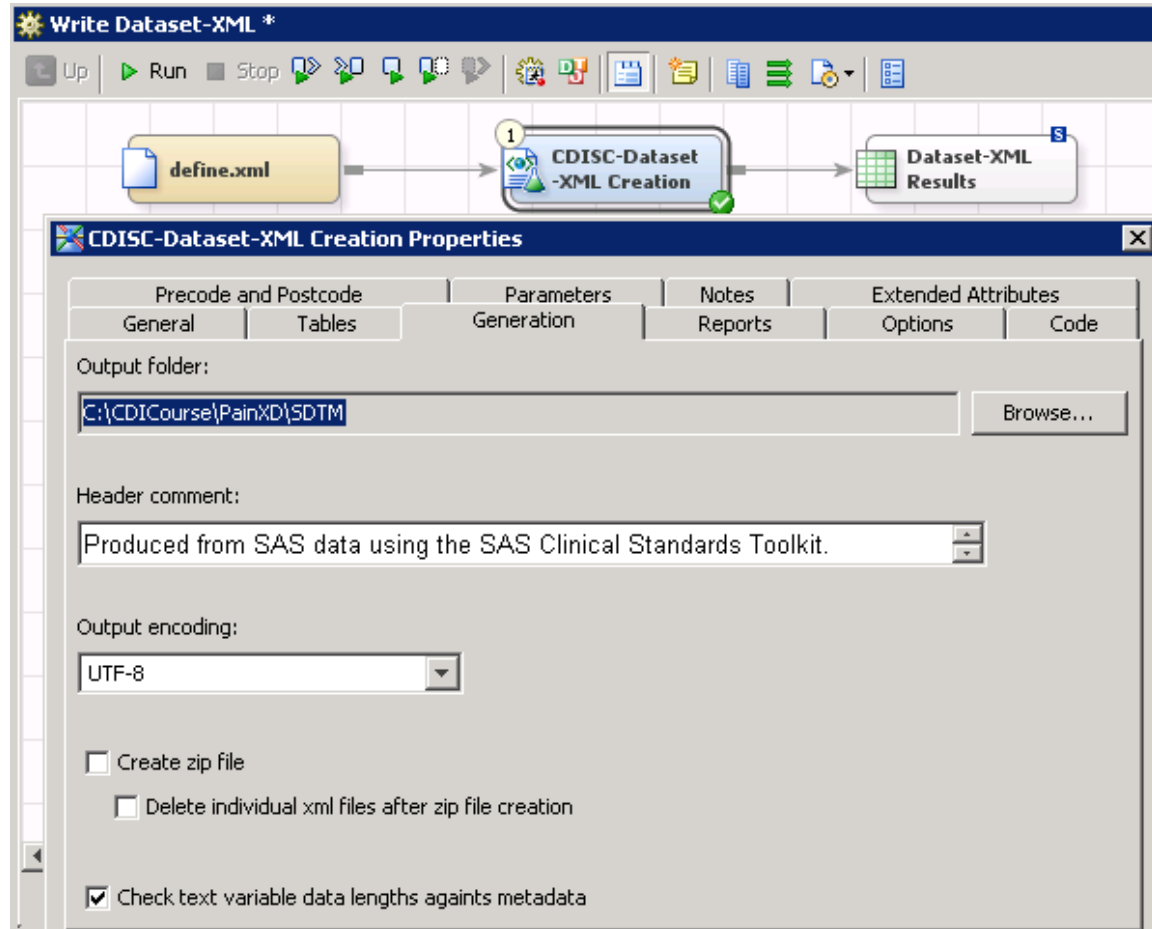
 <http://support.sas.com/base.cdisc./cst/index.html#papers1.7>

SAS® Clinical Standards Toolkit 1.7

The SAS® Clinical Standards Toolkit provides support of multiple CDISC standards, including SDTM (3.1.2, 3.1.3, and 3.2), CRT-DDS (reading and creating define 1.0 XML files), Define-XML 2.0 (reading and creating define 2.0 XML files), Dataset-XML (creating Dataset-XML files from SAS data sets and creating SAS data sets from Dataset-XML files), ODM (reading and creating 1.3.0 and 1.3.1 XML files), ADaM 2.1, CDASH 1.1, SEND 3.0, and validating XML files against an XML schema file. This tool is the platform used by SAS® to support Health and Life Sciences industry data model standards

SAS Tools for Dataset-XML

Clinical Data® Integration 2.6



SAS Tools for Dataset-XML

Available as stand alone macros

 <http://support.sas.com/kb/53/447.html>

Sample 53447: SAS® Macros to support Dataset-XML v1.0.0

Details

Downloads

About

Rate It

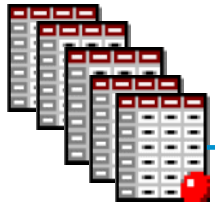
This package contains macros, XML schema files, sample data, and sample programs to support the following functionality:

- 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

Documentation is available in this file that is part of the ZIP file: [SAS-Dataset-XML-v1.0.0-support.pdf](#)

Dataset-XML SAS Tools to Write Dataset-XML

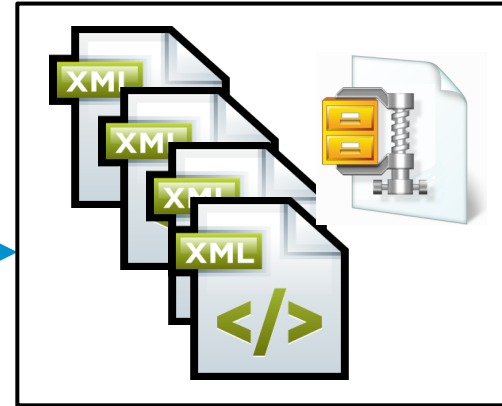
SAS Data



Define-XML

`%datasetxml_write()`

Dataset-XML



Dataset-XML SAS Tools to Write Dataset-XML

```
*****;  
* Create SDTM Dataset-XML files *;  
*****;  
libname sdtmdata "&studyRootPath/sasdata/original/sdtm";  
filename defxml "&studyOutputPath/xmldata/sdtm/define.xml";  
libname dataxml "&studyOutputPath/xmldata/sdtm";  
  
%datasetxml_write(  
  _cstSourceLibrary=sdtmdata,  
  _cstOutputLibrary=dataxml,  
  _cstSourceMetadataDefineFileRef=defxml,  
  _cstCheckLengths=Y,  
  _cstIndent=N,  
  _cstZip=Y,  
  _cstDeleteAfterZip=N  
);  
  
libname sdtmdata clear;  
filename defxml clear;  
libname dataxml clear;
```

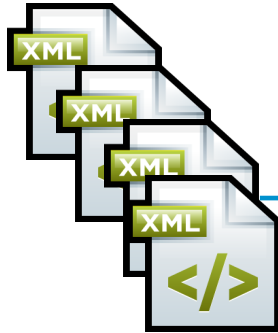
- `_cstCheckLengths` The actual value lengths of variables with `DataType=text` are checked against the lengths as defined in the metadata. If the lengths as defined in the metadata are too short, a warning is written to the log file (Y/N, default=N)

```
WARNING: [CSTLOGMESSAGE.DATASETXML_WRITE] Length too short:  
__ItemGroupOID=IG.ADAE __ItemOID=IT.ADAE.AETERM Length=20  
_valueLength=25 value=ACID REFLUX (OESOPHAGEAL)
```

- `_cstOutputEncoding` - The XML encoding to use for the Dataset-XML files to create (Default=UTF-8)
- `_cstIndent` - Indent the Dataset-XML file (Y/N, default=Y)
- `_cstNumericFormat` – the default format used to write numeric data (default=best32.)
- `_cstZip` - Zip the Dataset-XML file to a zip file in the same folder and with the same name as the Dataset-XML file (Y/N, default:N)

Dataset-XML SAS Tools to Read Dataset-XML

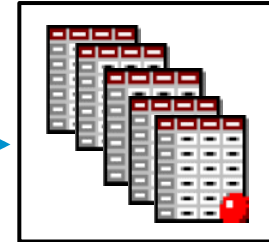
Dataset-XML



Define-XML

`%datasetxml_read()`

SAS Data



Dataset-XML SAS Tools to Read Dataset-XML

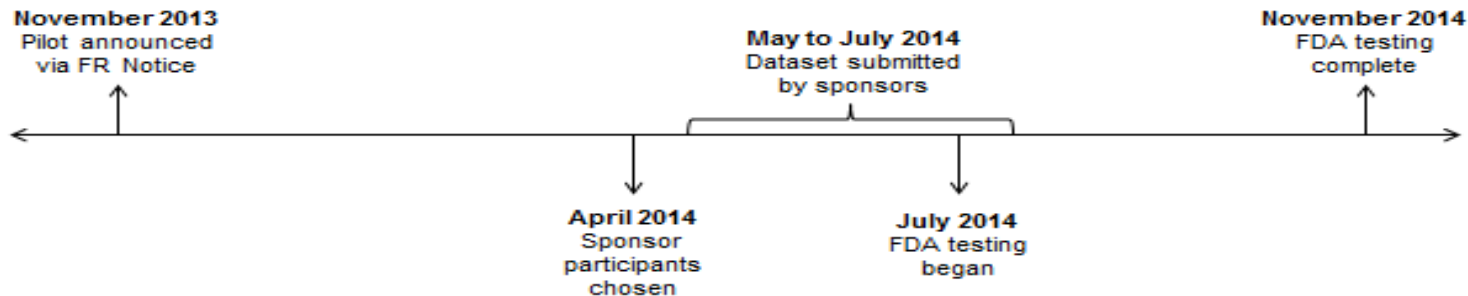
```
*****;  
* Create SDTM SAS Data sets *;  
*****;  
  
libname dataxml "&studyRootPath/xmldata/sdtm";  
libname sdtmdata "&studyRootPath/sasdata/imported/sdtm";  
filename defxml "&studyOutputPath/xmldata/sdtm/define.xml";  
  
%datasetxml read(  
  _cstSourceDatasetXMLLibrary=dataxml,  
  _cstOutputLibrary=sdtmdata,  
  _cstSourceMetadataDefineFileRef=defxml,  
  _cstdatetimeLength=64,  
  _cstAttachFormats=Y  
);  
  
libname dataxml clear;  
libname sdtmdata clear;  
filename defxml clear;
```

- `_cstDatetimeLength` - Character variables that represent Date/Time related information in ADaM/SDTM data conform to ISO 8601 standard and do not have a length specified in the Define-XML file. This macro parameter specifies the length to use for these variables when they are converted to SAS data sets.
- `_cstAttachFormats` - defines whether display formats, as defined in the Define-XML file, will be attached to the dataset variables.

FDA Pilot



- **Objectives:**
 - Conduct an evaluation of the CDISC Dataset-XML standard as a solution to the challenges of SAS XPORT V5 transport
 - Assess the technical capability of Dataset-XML to exchange and archive regulatory study data
 - Assess the capability of Dataset-XML to transport the FDA-supported study data standards (SDTM, SEND, ADaM) specified in the Data Standards Catalog



- 6 sponsors participated in the pilot.
- The sponsors **re-submitted** a previously submitted set of Phase 3 study **datasets** in the CDISC **Dataset-XML format**
- SAS entered a partnership with one of the sponsors
- SAS developed the software for their partner sponsor to create and validate Dataset-XML files

- Dataset-XML can
 - **transport** data and **maintain** data integrity.
 - facilitate a **longer variable** name (>8 characters), a **longer label** name (>40 characters) and **longer text** field (>200 characters).
- Dataset-XML requires
 - stricter encoding in data.
 - **consistency** between datasets and Define.xml.
- Dataset-XML produced
 - much **larger file** sizes than XPORT
 - which may impact the Electronic Submissions Gateway (ESG) and may lead to file storage issues.

- FDA envisions conducting several pilots to evaluate new transport formats before a decision is made to support a new format.



THANK YOU !

QUESTIONS ?

