



CDISC Dataset-XML Specification

Version 1.0

Prepared by

CDISC Dataset-XML Team

Notes to Readers

- This is the specification for Version 1.0 of the CDISC Dataset-XML standard.

Revision History

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).

Table of Contents

1 INTRODUCTION	4
1.1 PURPOSE OF THIS DOCUMENT.....	4
1.2 DATASET-XML RELEASE PACKAGE	4
1.3 DATASET-XML FOR DATA INTERCHANGE	4
1.3.1 <i>U.S. Electronic Submission Background</i>	4
1.3.2 <i>Format for Industry Data Interchange</i>	4
1.4 CDISC	5
1.5 RELATIONSHIPS TO OTHER CDISC STANDARDS	5
1.5.1 <i>Operational Data Model (ODM)</i>	5
1.5.2 <i>Define-XML</i>	5
1.5.3 <i>Study Data Tabulation Model (SDTM) Implementations</i>	6
1.5.4 <i>Analysis Data Model (ADaM)</i>	6
1.5.5 <i>Standard for Exchange of Nonclinical Data (SEND)</i>	6
2 ABBREVIATIONS AND REFERENCES	6
2.1 ABBREVIATIONS AND TERMS.....	6
2.2 REFERENCES	9
3 CONFORMITY AND GENERAL ISSUES	10
3.1 FILE CONFORMITY.....	10
3.2 EXTENSIONS	10
3.3 DATASET-XML DOCUMENT STRUCTURE	11
3.4 DATASET-XML AND DEFINE-XML	14
3.5 DATASET-XML AND SDTM, ADAM, AND SEND	14
3.6 OIDs	14
3.7 VALIDATION OF A DATASET-XML DOCUMENT	16
4 USING DATASET-XML.....	17
4.1 SUBJECT-LEVEL DATA	17
4.1.1 <i>Example of a Subject-Level Dataset (SDTM)</i>	17
4.2 REFERENCE DATA	19
4.2.1 <i>Example of a Reference Dataset</i>	19
4.3 REPRESENTING DATA VALUES	20
4.4 DATA TYPE CONSIDERATIONS	20
4.4.1 <i>Converting Floats for use in XML</i>	20
5 SPECIFICATION	21
5.1 DATASET-XML SCOPE.....	21
5.2 DATASET-XML STRUCTURE.....	21
5.3 DATASET-XML SPECIFICATION DETAILS	24
5.3.1 <i>XML Header</i>	24
Example XML Header	24
5.3.2 <i>ODM Element</i>	24
5.3.3 <i>ReferenceData Element</i>	26
5.3.4 <i>ItemGroupData Element</i>	26
5.3.5 <i>ItemData Element</i>	27
5.3.6 <i>ClinicalData Element</i>	28
6 ACKNOWLEDGMENTS	29

7 ODM CHANGES AND EXTENSIONS SUPPORTING DATASET-XML.....	29
8 APPENDICES	30
8.1 APPENDIX A: XML SCHEMA	30
8.2 APPENDIX B: REPRESENTATIONS AND WARRANTIES, LIMITATIONS OF LIABILITY, AND DISCLAIMERS	31

1 Introduction

1.1 Purpose of this document

This specification describes the CDISC standard Dataset-XML model that is used to provide study datasets in an XML format. The purpose of Dataset-XML is to support the interchange of tabular clinical research data using ODM-based XML technologies. The Dataset-XML model is based on the CDISC Operational Data Model (ODM) standard and follows the metadata structure defined in the Define-XML 2.0 standard.

1.2 Dataset-XML Release Package

The Dataset-XML release package includes:

- Dataset-XML v1.0 specification
- Dataset-XML v1.0 schema
- Dataset-XML v1.0 example files
- ODM v1.3.2 schema

1.3 Dataset-XML for Data Interchange

1.3.1 U.S. Electronic Submission Background

In the United States, the approval process for regulated human and animal health products requires the submission of data from clinical trials and other studies as expressed in the Code of Federal Regulations (CFR). The FDA established the regulatory basis for wholly electronic submission of data in 1997 with the publication of regulations on the use of electronic records in place of paper records (21 CFR Part 11). In 1999, the FDA standardized the submission of clinical and non-clinical data using the SAS XPORT Transport Format and the submission of metadata using Portable Document Format (PDF). In 2005, the *Study Data Specifications* published by the FDA included the recommendation that data definitions (metadata) be provided as a Define-XML file. On November 12, 2012, the FDA held a meeting entitled “Regulatory New Drug Review: Solutions for Study Data Exchange Standards”, the purpose of which was to solicit input regarding the advantages and disadvantages of current and emerging open, consensus-based standards for the exchange of regulated study data. Dataset-XML was presented as an ODM-based alternative for consideration.

For a current list of data and metadata requirements for FDA submission see <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions>.

1.3.2 Format for Industry Data Interchange

Dataset-XML defines an ODM-based standard format for transporting tabular dataset data in XML between any two entities. That is, in addition to supporting the transport of datasets as part of a submission to the FDA, it may also be used to facilitate other data interchange use cases. For example, the Dataset-XML data format can be used by a CRO to transmit SDTM or ADaM datasets to a sponsor organization. Dataset-XML supports SDTM, ADaM, and SEND CDISC datasets, but can also be used to exchange any other type of tabular dataset.

1.4 CDISC

The Clinical Data Interchange Standards Consortium (CDISC) is a non-profit organization whose mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.

The FDA has collaborated with CDISC since its founding in order to standardize the content and structure of clinical trials and non-clinical study data for regulatory submission. CDISC sponsors and members represent more than 250 companies active in the research and development of regulated health-related products.

1.5 Relationships to Other CDISC Standards

1.5.1 Operational Data Model (ODM)

The Dataset-XML standard is based on the CDISC Operational Data Model (ODM) XML schema. ODM is a vendor-neutral, platform-independent format for the interchange and archival of clinical study data. The model includes the clinical data along with its associated metadata, administrative data, reference data and audit information. ODM includes all of the information that needs to be shared among different software systems during study setup, operation, analysis, and submission or for long term retention as part of a study archive. ODM has been embraced by a broad range of clinical development organizations, and a number of vendors provide software applications and tools that use ODM. The current version of the ODM standard is available at <http://www.cdisc.org/odm>.

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 Dataset-XML model, which is implemented as a set of extensions to the base ODM 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 Dataset-XML standard are available online at <http://www.cdisc.org/Dataset-xml>.

While this document is intended to be understandable to readers with minimal technical knowledge of the ODM and XML, knowledge of this document alone is not a substitute for knowledge of the ODM. This document should be used in close concert with the current version of the ODM specification as well as current versions of the relevant CDISC data and metadata standards. Reading the ODM specification section 3.1.4 Clinical Data, at a minimum, is recommended. The ODM specification package, including the relevant schemas, is available online at <http://www.cdisc.org/odm>.

Numerous examples of XML fragments appear in this document. Many of these examples are provided as XML files and can be downloaded from the CDISC website (<http://www.cdisc.org/Dataset-xml>).

1.5.2 Define-XML

As with Dataset-XML, the Define-XML model is implemented using extensions to the CDISC Operational Data Model (ODM) XML schema. The Define-XML v2.0.0 specification describes a model that defines CDISC SDTM, SEND and ADaM datasets as well as accommodating any other tabular dataset structure. One of the key benefits to FDA reviewers is that this standard provides both a machine readable format for use by the various FDA software applications

and, through the provision of an XSL stylesheet, a browser-based report describing the contents of clinical study datasets.

Define-XML v2.0.0 can be used to transmit metadata for any tabular dataset, including the following CDISC standards:

- SDTM Implementation Guide Versions 3.1.2 and higher
- ADaM Implementation Guide Versions 1.0 and higher
- SEND Implementation Guide Versions 3.0 and higher.
- SDTM Implementation Guide for Medical Devices Version 1.0 and higher

Define-XML v2.0 and later are recommended for use with Dataset-XML.

1.5.3 Study Data Tabulation Model (SDTM) Implementations

Dataset-XML can be used to transmit data based on the SDTM Implementation Guide Versions 3.1.2 and higher, and other IGs based on SDTM. SDTM defines a standard structure for case report form data tabulations that are required to be submitted as part of a product application to the FDA. The CDISC SDTM is used to submit clinical trial and non-clinical study data for product applications across all therapeutic areas. The current version of the SDTM and SDTMIG standards are available at <http://www.cdisc.org/sdtm>.

1.5.4 Analysis Data Model (ADaM)

Dataset-XML can be used to transmit ADaM data based on the ADaM Implementation Guide versions 1.0 and higher. ADaM defines standards for analysis datasets that are submitted as part of a product application to the FDA. In addition to defining fundamental principles that apply to all analysis datasets, ADaM defines standard structures that are appropriate for the majority of analysis datasets. Because analysis datasets are developed to support specific analyses, ADaM has additional metadata that is not found in SDTM or SEND, notably analysis results metadata. Additionally, the metadata to describe variable sources and derivations is of primary importance.

The current version of the ADaM standard is available at <http://www.cdisc.org/adam>.

1.5.5 Standard for Exchange of Nonclinical Data (SEND)

Dataset-XML can be used to transmit SEND data based on the SEND Implementation Guide versions 3.0 and higher. SEND is an implementation of SDTM for non-clinical studies, which specifies a way to present non-clinical data in a consistent format. This type of study is typically related to animal testing as part of pre-clinical (pre-Phase 1) trials. SEND datasets may be included as part of a product application to the FDA.

The current version of the SEND Implementation Guide is available at <http://www.cdisc.org/send>.

2 Abbreviations and References

2.1 Abbreviations and Terms

ADaM	Analysis Data Model - developed by CDISC.
ADaMIG	Analysis Data Model Implementation Guide – developed by CDISC
CRF	Case Report Form
CRO	Contract Research Organization
CRT	Case Report Tabulation
define.xml	An instance of a Define-XML document. See Define-XML.
Define-XML	Define-XML is the CDISC standard for transmission of metadata for SDTM, SEND, ADaM, and any other tabular datasets.
eCTD	Electronic Common Technical Document
FDA	United States Food and Drug Administration
ICH	International Conference on Harmonization of technical requirements for registration of pharmaceuticals for human use.
ODM	Operational Data Model – developed by CDISC as an XML format for the transmission and archival of clinical trials data and metadata.
OID	ODM element identifier.
PDF	Portable Document Format – an open standard for document exchange developed by Adobe Systems
Dataset-XML	Dataset-XML supports the interchange of tabular clinical research data using ODM-based XML technology.
SDTM	Study Data Tabulation Model – developed by CDISC for the purpose of submitting Study Data Tabulations to the United States Food and Drug Administration.
SDTM-MSG	Study Data Tabulation Model Metadata Submission Guidelines – developed by CDISC
SDTMIG	Study Data Tabulation Model Implementation Guide – developed by CDISC
SDTMIGMD	Study Data Tabulation Model Implementation Guide for Medical Devices – developed by CDISC
SEND	Standard for Exchange of Non-clinical Data – developed by CDISC
URI	Uniform Resource Identifier - a string of characters used to identify a resource on the internet
URL	Uniform Resource Locator
W3C	World Wide Web Consortium
XLink	XML Linking Language – developed by the W3C

XML	Extensible Markup Language - developed by the W3C
XPT	SAS Transport (XPORT) Format – an open standard for data transmission developed and maintained by SAS (see http://support.sas.com/techsup/technote/ts140.html)
XSD	XML Schema Definition (see http://en.wikipedia.org/wiki/XML_Schema_(W3C))
XSL	Extensible Stylesheet Language – developed by the W3C for the purpose of transforming and formatting XML documents

2.2 References

The documents referenced during the development of this Dataset-XML Specification may be accessed via the links provided below.

- CDISC website
<http://www.cdisc.org>
- ODM Version 1.3.2
<http://www.cdisc.org/odm>
- Define-XML Versions 1.0 & 2.0
<http://www.cdisc.org/define-xml>
- SDTM - Study Data Tabulation Model (SDTM) Final Version 1.2
<http://www.cdisc.org/sdtm>
- SDTM-IG - CDISC SDTM Implementation Guide Version 3.1.2
<http://www.cdisc.org/sdtm>
- SDTM-MSG – SDTM Metadata Submission Guidelines V1
<http://www.cdisc.org/sdtm>
- SDTMIG-MD – SDTM Implementation Guide for Medical Devices Version 1.0
<http://www.cdisc.org/sdtm>
- ADaM - CDISC Analysis Data Model (ADaM) Version 2.1
<http://www.cdisc.org/adam>
- ADaM-IG - CDISC Analysis Data Model (ADaM) Implementation Guide Version 1.0
<http://www.cdisc.org/adam>
- SEND-IG - CDISC SEND Implementation Guide Version 3.0
<http://www.cdisc.org/send>
- Controlled Terminology
<http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>
- XML Schema Validation for Define.xml White Paper
<http://www.cdisc.org/define-xml>
- FDA eCTD Guidance - Electronic Common Technical Document
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072349.pdf>
- FDA Study Data Specifications
<http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM312964.pdf>
- FDA Study Data Standards Page
<http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>

3 Conformity and General Issues

This section supplements the corresponding section, “General Issues”, of the ODM v1.3.2 specification.

All conformity requirements described in the ODM v1.3.2 specification are also applicable to Dataset-XML files unless stated otherwise.

3.1 File Conformity

The namespace URI for version 1.0.0 of Dataset-XML is:
<http://www.cdisc.org/ns/Dataset-XML/v1.0>.

Throughout this document, the following conventions are used for namespaces:

- ODM elements and attributes are in the default namespace (i.e. they have no namespace prefix)
- Dataset-XML elements use the namespace prefix “data”
- Dataset-XML attributes use the namespace prefix “data” only if they appear within ODM elements

Note that these namespace prefixes are used throughout this document and are recommended as best practice both to make it easier for users to understand and implement Dataset-XML, and to aid in the comparison of documents.

Any XML included in a Dataset-XML document that is not described in this specification is considered an extension.

Deprecated elements or attributes are not valid for use and are considered errors.

3.2 Extensions

The Dataset-XML schema permits vendor extensions, as defined in the ODM v1.3.2 specification, to the elements defined in this specification. These extensions may take the form of CDISC-created extensions, such as the Analysis Results Metadata extension currently under development, or vendor extensions. Any XML not explicitly specified as part of Dataset-XML v1.0.0 is considered an extension. This includes ODM metadata not explicitly referenced in this specification. Extensions have no implied meaning with respect to the Dataset-XML standard; the sender and receiver must agree on a meaning between themselves. That is, *Dataset-XML* files that use extensions are not wrong, but instead the extensions may be ignored unless the sender and receiver have agreed otherwise. This also means that validators should flag ODM metadata not explicitly mentioned in the Dataset-XML specification with informational messages, and not with errors or warnings.

Requirements for vendor extensions to the Dataset-XML schema are:

- The vendor must supply an XML Schema fully describing their extended Dataset-XML format if it uses extended elements or attributes not already defined in the ODM namespace or Dataset-XML extension.
- Extended Dataset-XML files should reference the proper extension schema.

- The extension may add new XML elements and attributes, but may not render any standard Dataset-XML elements or attributes obsolete. Vendor extensions may not be used for information that is normally expressed using other Dataset-XML elements or attributes.
- Elements and attributes from the ODM schema that are not a part of the Dataset-XML schema can be used as extensions, but no elements or attributes can be added to the ODM or Dataset-XML namespaces.
- All extension elements and attributes not already defined in the ODM namespace must use a distinct XML namespace to ensure that there are no naming conflicts with other vendor extensions.
- The meaning of a Dataset-XML file must not be fundamentally changed by the addition of extensions.
- Removing all vendor extensions from an extended Dataset-XML file must result in a valid, meaningful and accurate Dataset-XML file.
- Vendors should be able to produce Dataset-XML files free of any vendor extensions upon request.

3.3 Dataset-XML Document Structure

The examples below show the basic structure of any ODM v1.3.2 document that contains Dataset-XML content. Each example illustrates a valid Dataset-XML header and a single dataset row. Example 3.3.1 shows data for the CM (Concomitant Medications) domain. Since this is study subject data, the ItemGroupData element appears under the [ClinicalData element](#). Example 3.3.2 shows data from the TA (Trial Arms) domain. Since this is not subject related data, the ItemGroupData element appears under the [ReferenceData element](#). Note that the value of MetaDataVersionOID for both examples is the same as the value of the OID attribute in the Define-XML MetaDataVersion element provided with the accompanying examples.

Example 3.3.1: Dataset-XML document structure using the ClinicalData element

```
<?xml version="1.0" encoding="UTF-8"?>
<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"
  FileOID="www.cdisc.org.Studycdisc01-Define-XML_2.0.0(IG.CM)"
  PriorFileOID="www.cdisc.org.Studycdisc01-Define-XML_2.0.0"
  Originator="CDISC Dataset-XML Team"
  CreationDateTime="2014-03-20T21:45:33">
  <ClinicalData
    StudyOID="cdisc01"
    MetaDataVersionOID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2">
    <!-- Dataset (CM) -->
    <ItemGroupData ItemGroupOID="IG.CM" data:ItemGroupDataSeq="1">
      <ItemData ItemOID="IT.STUDYID" Value="CDISC01"/>
      <ItemData ItemOID="IT.CM.DOMAIN" Value="CM"/>
      <ItemData ItemOID="IT.USUBJID" Value="CDISC01.100008"/>
      <ItemData ItemOID="IT.CM.CMSEQ" Value="1"/>
      <ItemData ItemOID="IT.CM.CMTRT" Value="PROCARDIA XL"/>
      ...
    </ItemGroupData>
    ...
  </ClinicalData>
</ODM>
```

Example 3.3.2: Dataset-XML document structure using ReferenceData

```
<?xml version="1.0" encoding="UTF-8"?>
<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"
  FileOID="www.cdisc.org.Studycdisc01-Define-XML_2.0.0(IG.TA)"
  PriorFileOID="www.cdisc.org.Studycdisc01-Define-XML_2.0.0"
  Originator="CDISC Dataset-XML Team"
  CreationDateTime="2014-03-20T21:45:33" >
  <ReferenceData
    StudyOID="cdisc01"
    MetaDataVersionOID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2">
    <!-- Dataset (TA) -->
    <ItemGroupData ItemGroupOID="IG.TA" data:ItemGroupDataSeq="1">
      <ItemData ItemOID="IT.STUDYID" Value="CDISC01"/>
      <ItemData ItemOID="IT.TA.DOMAIN" Value="TA"/>
      <ItemData ItemOID="IT.TA.ARMCD" Value="PLACEBO"/>
      <ItemData ItemOID="IT.TA.ARM" Value="Placebo"/>
      <ItemData ItemOID="IT.TA.TAETORD" Value="1"/>
      <ItemData ItemOID="IT.TA.ETCD" Value="SCREEN"/>
      <ItemData ItemOID="IT.TA.ELEMENT" Value="Screening"/>
      <ItemData ItemOID="IT.TA.EPOCH" Value="SCREEN"/>
    </ItemGroupData>
    ...
  </ReferenceData>
</ODM>
```

3.4 Dataset-XML and Define-XML

Dataset-XML defines a standard format for transporting tabular dataset data in XML. The metadata for a dataset contained within an Dataset-XML document must be specified using the Define-XML standard. The Define-XML must be contained within the same folder as the dataset document files. Each Dataset-XML file contains data for a single dataset but a single *define.xml* file describes all the datasets included in the folder. The Dataset-XML file containing the data may be linked to the *define.xml* file containing the metadata by the PriorFileOID attribute on the root ODM node.

Define-XML v2.0 and later are recommended for use with Dataset-XML. The current production version of Define-XML is version 2.0.

3.5 Dataset-XML and SDTM, ADaM, and SEND

Dataset-XML can be used to transport any tabular data. This includes, but is not limited to, SDTM, ADaM, and SEND datasets.

3.6 OIDs

Attributes whose names end with “OID” are used to uniquely identify specific metadata objects. For example, in the ItemData XML element (described in section 5.3.5) the ItemOID attribute references a specific ItemDef in the *define.xml* file containing the variable metadata. Although the examples in this document use prefixes in the OIDs to indicate the object type, this is not required. The value of the OID attribute has no meaning by itself.

In the example below, with corresponding numbers highlighted in green, we can see that in the *ae.xml* document the ClinicalData attributes StudyOID and MetaDataVersionOID must have the same value as the corresponding OID attributes in the *define.xml* document. We also see that the ItemGroupOID value has to be the same as the corresponding ItemGroup OID attribute value. Finally, we see that all ItemOID attributes in Itemdata elements in the *ae.xml* document have values identical to the values of corresponding ItemOID attributes in ItemRef elements that are child elements of the corresponding ItemGroupDef element in the *define.xml* document.

define.xml document:

```

<ODM ...
    <Study OID="cdisc01"> ←1
        <GlobalVariables>
            <StudyName>CDISC01</StudyName>
            <StudyDescription>CDISC Test Study</StudyDescription>
            <ProtocolName>CDISC01</ProtocolName>
        </GlobalVariables>
        <MetaDataVersion OID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2" ...> ←2
            ...
            <ItemGroupDef OID="IG.AE" ←3
                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" KeySequence="1"/>
                <ItemRef ItemOID="IT.AE.DOMAIN" OrderNumber="2" Mandatory="Yes"/>
                <ItemRef ItemOID="IT.USUBJID" OrderNumber="3" Mandatory="Yes" KeySequence="2"
                    MethodOID="MT.USUBJID"/>
            ...
            ←4
                <ItemRef ItemOID="IT.AE.AETERM" OrderNumber="6" Mandatory="Yes"/>
                <ItemRef ItemOID="IT.AE.AEMODIFY" OrderNumber="7" Mandatory="No"/>
                <ItemRef ItemOID="IT.AE.AEDECOD" OrderNumber="8" Mandatory="Yes" KeySequence="3"/>
            ...
            <def:leaf ID="LF.AE" xlink:href="ae.xml">
                <def:title>ae.xml</def:title>
            </def:leaf>
        </ItemGroupDef>
    </ODM>

```

ae.xml document:

```

<ODM ...
    <ClinicalData
        StudyOID="cdisc01" ←1
        MetaDataVersionOID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2"> ←2
        <ItemGroupData ItemGroupOID="IG.AE" ←3 data:ItemGroupDataSeq="1">
            <ItemData ItemOID="IT.STUDYID" Value="CDISC01"/>
            <ItemData ItemOID="IT.AE.DOMAIN" Value="AE"/>
            <ItemData ItemOID="IT.USUBJID" Value="CDISC01.100008"/>
        ...
        ←4
            <ItemData ItemOID="IT.AE.AETERM" Value="AGITATED"/>
            <ItemData ItemOID="IT.AE.AEMODIFY" Value="AGITATION"/>
            <ItemData ItemOID="IT.AE.AEDECOD" Value="Agitation"/>
        ...
    </ItemGroupData>
</ODM>

```

3.7 Validation of a Dataset-XML document

A valid Dataset-XML document must:

- Properly reference versions of the CDISC standards.
- Be well formed and conform to the XML schemas.
- Meet all of the requirements documented in this specification.

Once an Dataset-XML document is valid according to the schema, validation software should consider all Dataset-XML requirements in the specification. These include rules about conditionally required components and other business rules specified within this document. Schema validation can only enforce some parts of the standard, so this additional level of validation is required to determine whether a Dataset-XML document is fully compliant with Dataset-XML v1.0.0. See the [XML Schema Validation for Define.xml](#) White Paper for additional information.

The correct ordering of elements within a document is an absolute requirement for the document to be valid with respect to the Dataset-XML schema. The use of an XML schema definition and a validating parser environment makes detection of improperly ordered content fairly straightforward. In the absence of such mechanisms, care should be extended to following the order specified by the documentation for all extension content.

Note that XML is case sensitive, and case sensitivity plays a role in creating a valid Dataset-XML file. For example, ItemGroupOID="DM" is not the same as ItemGroupOID="dm".

4 Using Dataset-XML

The purpose of Dataset-XML is to support the interchange of tabular data for clinical research applications using ODM-based XML technologies. Dataset-XML offers an alternative to SAS XPT Transport Format files for submitting data to the FDA.

The data exchanged using the Dataset-XML standard is expected to match the metadata definitions provided in the *define.xml* document included in the Dataset-XML folder.

Each record in a dataset is represented by an *ItemGroupData* element with a unique *data:ItemGroupDataSeq* attribute. The *ItemGroupOID* attribute references an *ItemGroupDef* within the *define.xml* document that contains the dataset metadata. Dataset-XML can represent any tabular dataset that can be described using Define-XML, including SDTM, ADaM, SEND, or non-standard legacy datasets.

Each dataset variable value within a dataset record is represented with an *ItemData* element where the *ItemOID* attribute references an *ItemDef* within the Define-XML file that provides the variable metadata. Dataset variables with missing or null values are exceptions to this rule and are not included as *ItemData* elements.

The underlying ODM standard provides two ways to represent data – Typed and Untyped. Only the Untyped representation of ODM data may currently be used with Dataset-XML.

The Dataset-XML examples were developed using the original SAS XPT files published in SDTM-MSG V1. These example files are included in the Dataset-XML release package. A *define.xml* v2.0 document accompanies the example files, and provides the metadata for the Dataset-XML files. This *define.xml* document is a revised version of the example file distributed with the Define-XML Version 2.0 release package. Note that most data examples in this document are segments extracted from the Dataset-XML examples files.

When datasets are delivered as Dataset-XML, any SDTM, ADaM or SEND validation tool is expected to report the same findings as it would when the datasets are delivered using other formats, such as SAS XPT.

4.1 Subject-Level Data

Study subject data for SDTM, SEND or ADaM datasets should be placed under the *ClinicalData* element in the Dataset-XML documents. For datasets that contain non-subject specific information, such as the Trial Design domains, the data should be placed under a *ReferenceData* element in the Dataset-XML documents, and the *IsReferenceData* attribute in the *ItemGroupDef* element must be set to "Yes".

4.1.1 Example of a Subject-Level Dataset (SDTM)

The example below corresponds to the AE dataset and shows two Adverse Event records (records 1 and 16, as indicated by *data:ItemDataGroupSeq*). Of the two records shown, the first contains 16 item data values and the second contains 15 item data values.

- The ItemGroupOID attribute in the ItemGroupData element corresponds to the ItemGroupDef/@OID="IG.AE" in the *define.xml* document.
- The data:ItemGroupDataSeq attribute indicates the dataset record row number.
- Missing values, and null values, are not included as an ItemData element.
 - In the record represented with data:ItemGroupDataSeq=1, there are no ItemData elements corresponding to variables (ItemDef elements) "AEENDTC" and "AEENDY".
 - In the record represented with data:ItemGroupDataSeq=16, there are no ItemData elements corresponding to variables (ItemDef elements) "AEMODIFY", "AEENDTC" and "AEENDY".

```

<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"/>
    <ItemData ItemOID="IT.AE.AEMODIFY" Value="AGITATION"/>
    <ItemData ItemOID="IT.AE.AEDECOD" Value="Agitation"/>
    <ItemData ItemOID="IT.AE.AEBODSYS" Value="Psychiatric disorders"/>
    <ItemData ItemOID="IT.AE.AESEV" Value="MILD"/>
    <ItemData ItemOID="IT.AE.AESER" Value="N"/>
    <ItemData ItemOID="IT.AE.AEACN" Value="DOSE NOT CHANGED"/>
    <ItemData ItemOID="IT.AE.AEREL" Value="POSSIBLY RELATED"/>
    <ItemData ItemOID="IT.AE.AESTDTC" Value="2003-05"/>
    <ItemData ItemOID="IT.AE.AESTDY" Value="3"/>
    <ItemData ItemOID="IT.AE.AEENRF" Value="AFTER"/>
  </ItemGroupData>
  ...
  <ItemGroupData ItemGroupOID="IG.AE" data:ItemGroupDataSeq="16">
    <ItemData ItemOID="IT.STUDYID" Value="CDISC01"/>
    <ItemData ItemOID="IT.AE.DOMAIN" Value="AE"/>
    <ItemData ItemOID="IT.USUBJID" Value="CDISC01.200002"/>
    <ItemData ItemOID="IT.AE.AESEQ" Value="3"/>
    <ItemData ItemOID="IT.AE.AESPID" Value="2"/>
    <ItemData ItemOID="IT.AE.AETERM" Value="PALPITATIONS INTERMITTENT"/>
    <ItemData ItemOID="IT.AE.AEDECOD" Value="Palpitations"/>
    <ItemData ItemOID="IT.AE.AEBODSYS" Value="Cardiac disorders"/>
    <ItemData ItemOID="IT.AE.AESEV" Value="MILD"/>
    <ItemData ItemOID="IT.AE.AESER" Value="N"/>
    <ItemData ItemOID="IT.AE.AEACN" Value="DOSE NOT CHANGED"/>
    <ItemData ItemOID="IT.AE.AEREL" Value="NOT RELATED"/>
    <ItemData ItemOID="IT.AE.AESTDTC" Value="2004-01-05"/>
    <ItemData ItemOID="IT.AE.AESTDY" Value="88"/>
    <ItemData ItemOID="IT.AE.AEENRF" Value="AFTER"/>
  </ItemGroupData>
</ClinicalData>

```

4.2 Reference Data

Reference data is data that is not about clinical study subjects. Examples include SDTM Trial Design datasets, a dataset with Lab Reference Ranges, or a dataset with reference information about a medical device such as Device Identifiers, Device Tracking or Device Properties. In cases where the ItemGroupDef IsReferenceData attribute is set to "Yes", the data will be contained within the ReferenceData element instead of the ClinicalData element.

4.2.1 Example of a Reference Dataset

The example below corresponds to the TA dataset, which contains 8 item data values for the first TA record and 9 item data values for the second TA record.

- The OID in the ItemGroupData must correspond to an ItemGroupDef whose OID attribute value is "IG.TA" in the *define.xml* document.
- Missing values are not included as an ItemData.
 - In the record represented with data:ItemGroupDataSeq=1, there are no ItemData elements corresponding to variables (ItemDef elements) "TABRANCH" and "TATRANS".
 - In the record represented with data:ItemGroupDataSeq=9, there are no ItemData elements corresponding to variable (ItemDef element) "TATRANS".

```

<ReferenceData
  StudyOID="cdisc01"
  MetaDataVersionOID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2">
  <!-- Dataset (TA) -->
  <ItemGroupData ItemGroupOID="IG.TA" data:ItemGroupDataSeq="1">
    <ItemData ItemOID="IT.STUDYID" Value="CDISC01"/>
    <ItemData ItemOID="IT.TA.DOMAIN" Value="TA"/>
    <ItemData ItemOID="IT.TA.ARMCD" Value="PLACEBO"/>
    <ItemData ItemOID="IT.TA.ARM" Value="Placebo"/>
    <ItemData ItemOID="IT.TA.TAETORD" Value="1"/>
    <ItemData ItemOID="IT.TA.ETCD" Value="SCREEN"/>
    <ItemData ItemOID="IT.TA.ELEMENT" Value="Screening"/>
    <ItemData ItemOID="IT.TA.EPOCH" Value="SCREEN"/>
  </ItemGroupData> ...
  <ItemGroupData ItemGroupOID="IG.TA" data:ItemGroupDataSeq="9">
    <ItemData ItemOID="IT.STUDYID" Value="CDISC01"/>
    <ItemData ItemOID="IT.TA.DOMAIN" Value="TA"/>
    <ItemData ItemOID="IT.TA.ARMCD" Value="WONDER20"/>
    <ItemData ItemOID="IT.TA.ARM" Value="Miracle Drug 20 mg"/>
    <ItemData ItemOID="IT.TA.TAETORD" Value="3"/>
    <ItemData ItemOID="IT.TA.ETCD" Value="EOS"/>
    <ItemData ItemOID="IT.TA.ELEMENT" Value="End of Study"/>
    <ItemData ItemOID="IT.TA.TABRANCH" Value="Termination from study"/>
    <ItemData ItemOID="IT.TA.EPOCH" Value="TREATMENT"/>
  </ItemGroupData>
</ReferenceData>

```

4.3 Representing Data Values

The CDISC ODM supports two different modes of data transmission that are referred to as typed or untyped. For Dataset-XML, only untyped data is currently supported.

4.4 Data Type Considerations

CDISC SDTM, SEND and ADaM variable data types are specified as either character or numeric ("Char" and "Num", respectively). Define-XML supports a richer set of data types because it is based on the CDISC ODM. Refer to Section 4.2.1 "Data Type Considerations" in the Define-XML specification for information about allowed Data Types.

4.4.1 Converting Floats for use in XML

Each Dataset-XML ItemData element is defined by its corresponding ItemDef element in the associated *define.xml* file. The ItemDef element has a DataType attribute that specifies how the corresponding ItemData Value attribute is to be interpreted for comparison and storage. When data is represented in a binary format, like a SAS XPT file or database table, it must be converted to text for inclusion as a value in a Dataset-XML document. Conversely, Dataset-XML ItemData values may need to be converted into a binary format, such as in a SAS dataset. Typically, these values are converted with no loss or change in value. However, with the float datatype the number of significant digits must be included in the ItemDef element using the SignificantDigits and Length attributes to ensure the conversion is completed without data loss. Please refer to the Define-XML v2.0 specification for more details on the SignificantDigits and Length attributes.

5 Specification

5.1 Dataset-XML Scope

A Dataset-XML document provides the data for a single SDTM domain, an ADaM or SEND dataset, or a proprietary tabular dataset. This standard has been developed as an alternative to SAS XPT files used in the context of a regulatory submission of SDTM, ADaM, or SEND data. A set of Dataset-XML files would be expected to represent the data for one study. The Dataset-XML files needed to provide the data for a study would be determined by the standard represented, such as SDTM, and the study design. The metadata for Dataset-XML is provided in an accompanying Define-XML file.

5.2 Dataset-XML Structure

Dataset-XML is based on the CDISC ODM standard, and uses a simplified version of the traditional ODM structure to represent clinical datasets such as SDTM, ADaM, or SEND.

A Dataset-XML file includes the following components:

- XML header
- ODM root element
- ReferenceData
- ClinicalData
- ItemGroupData
- ItemData

Note that the components listed above do not include metadata. The metadata that describes the Dataset-XML document is contained in the associated Define-XML file. Also note that the typical ODM hierarchy for clinical data is simplified in Dataset-XML. The ODM hierarchy

ClinicalData/SubjectData/StudyEventData/FormDataTable/ItemGroupData/ItemData

is simplified to

ClinicalData/ItemGroupData/ItemData.

The sections that follow describe the content of an Dataset-XML document. Each of the the following sections describes the elements in the order in which they occur in the XML. Elements that may be used in more than one context are presented where they first appear in the document. The organization of the elements in this specification document does not reflect the hierarchical XML structure.

Each section begins with a brief description of the element followed by an *element table*, and an *attribute table*. The examples are provided in Section 4 General Specifications for Dataset-XML.

An *element table* describes the different aspects of an element's definition while the *attribute table* describes the element's attributes. The following templates illustrate the layouts of these tables, including the header and a description of the content.

Element Table Template

Element Name:	<i>Name of the element</i>
Element XPath:	<i>XPath showing where the element belongs in the XML</i>
Element Textual Value:	<i>A description of the value of the element. If an element has no text value (e.g. it has child elements instead), then this cell is populated with "None".</i>
Usage:	<p><u>Requirement:</u> <i>This is populated with one of three values:</i></p> <ul style="list-style-type: none"> • “Required” when at least one instance of the element is required • “Optional” when the element is optional • “Conditional” when at least one instance of the element is required under certain conditions. It will include the conditions under which the element is Required. <p><u>Cardinality:</u> <i>This indicates the number of instances expected (e.g. “Exactly One”, “One or more”, etc.)</i></p> <p><u>Business Rule(s):</u> <i>This is populated with rules that have to be satisfied in addition to an XML schema validation for a Dataset-XML document to be considered compliant with the Dataset-XML v1.0.0 specification.</i></p> <p><u>Other Information:</u> <i>This is populated with any other information about the element, including the conditions under which the element is included, how the schema is applied to support the model, relative position of the element in the model, etc.</i></p>
Attributes:	<i>A comma-delimited list of the attributes of this element. If the element has no attributes, this is populated with “None”.</i>
Child Elements:	<p><i>A comma-delimited list of the immediate child elements of this element. If the element has no child elements, this is populated with “None”. The order of child elements shown in the specification is the order in which they must appear in an Dataset-XML document.</i></p> <p><i>A link to a child element will be provided when the child element is described in a different section of the document and not under a sub-section of the element being described or in the section or subsection immediately following the current element.</i></p>

Attribute Table Template

Attribute	Usage	Allowable Values	Description
<p><i>Name of the attribute</i></p> <p><i>This is populated with “Required” when the attribute is required, “Optional” when the attribute is optional, or “Conditional” when the attribute is required under certain conditions.</i></p> <p><i>It will include the conditions under which the attribute is Required.</i></p> <p><i><u>Default:</u> This will be populated with a default value if one is provided in the specification.</i></p>	<p><i>Any combination of the following:</i></p> <p><u>Allowable Value:</u> The only allowed value</p> <p><u>Allowable Values:</u> A comma-delimited list of the allowable values</p> <p><u>Value Description:</u> A textual description of allowable values</p> <p><u>See Appendix xx:</u> A reference to an appendix including a hyperlink to the appendix</p> <p><u>Sample:</u> An example</p>	<p><i>A textual description of the attribute beyond what is included in the Allowable Values column.</i></p> <p>Business Rule(s): Rules that have to be satisfied in addition to schema validation for an Dataset-XML document to be considered compliant with the Dataset-XML v1.0.0 specification.</p>	

5.3 Dataset-XML Specification Details

5.3.1 XML Header

The first line of an Dataset-XML file must be the XML header. The XML header indicates that the remainder of the file is XML and specifies the character encoding it uses.

Example XML Header

```
<?xml version="1.0" encoding="UTF-8"?>
```

This example shows an Dataset-XML file using the "UTF-8" character encoding.

5.3.2 ODM Element

The first XML element in a file is known as the root element. In Dataset-XML the ODM element is the root element. The ODM element identifies the namespaces used, and includes attributes that affect the processing of the document as a whole.

Element Name:	ODM
Element XPath:	/ODM
Element Textual Value:	<i>None</i>
Usage:	<u>Requirement:</u> Required <u>Cardinality:</u> Exactly one <u>Other Information:</u> This is the root element for the Dataset-XML document
Attributes:	xmlns, xmlns:data, xmlns:xlink, xmlns:xsi, xsi:schemalocation, ODMVersion, FileType, FileOID, PriorFileOID, CreationDateTime, AsOfDateTime, Originator, SourceSystem, SourceSystemVersion, data:DatasetXMLVersion
Child Elements:	ReferenceData, ClinicalData

Attribute	Usage	Allowable Values	Description
xmlns	Required	"http://www.cdisc.org/ns/odm/v1.3"	Identifies the default namespace for this document.
xmlns:data	Required	"http://www.cdisc.org/ns/Dataset-XML/v1.0"	XML namespace for Dataset-XML v1.0.0. While "data:" is the suggested prefix for the Dataset-XML namespace, it should not be relied upon by the receiving application. The namespace prefix should follow the W3C naming requirements.
xmlns:xlink	Conditional Required when xlink:href is provided.	"http://www.w3.org/1999/xlink"	XML namespace for XLink.
xmlns:xsi	Conditional Required when xsi:schemalocation is provided.	"http://www.w3.org/2001/XMLSchema-instance"	XML Schema instance namespace. Required when xsi:schemalocation is provided.

xsi:schemalocation	Optional	Text <u>Sample:</u> "http://www.cdisc.org/ns/Dataset-XML/v1.0/dataset1-0-0.xsd"	Identifies the location of the schema for this XML document. The first part is the Namespace URI, and the second part is the location of the schema either on the internet (e.g. http://www.abc.com/dataset1-0-0.xsd) or on the local file system (e.g. dataset1-0-0.xsd). Using a local copy of the schema rather than referencing a schema using a URL on the web is recommended as it improves the probability that the software validating the Dataset-XML instance can find and access the appropriate files. However, when submitting Dataset-XML files to a regulatory authority, be aware that relative file references or references to a shared drive on a local area network may not work when the submission contents are transmitted to a different network location.
ODMVersion	Required	"1.3.2"	Identifies the ODM version that underlies the schema for the Dataset-XML document. ODMVersion is optional in the ODM standard, but required in Dataset-XML.
FileType	Required	"Snapshot"	Dataset-XML documents do not include audit trail elements, so the FileType is Snapshot .
FileOID	Required	Text	A unique identifier for this file. See the ODM specification for a discussion of FileOID recommendations.
PriorFileOID	Optional	Text	A unique identifier for the Define-XML file. <u>Business Rule:</u> The Dataset-XML PriorFileOID may contain a link to the Define-XML file containing the metadata for the datasets.
CreationDateTime	Required	ISO8601 datetime <u>Sample:</u> "2013-09-30T15:31:04"	The date and time when the specific version of the Dataset-XML file was created. This is the "last modified" date and time.
AsOfDateTime	Optional	ISO8601 datetime <u>Sample:</u> "2013-09-30T15:31:04"	The date and time at which the source database was queried to create this document.
Originator	Optional	Text <u>Sample:</u> "Company XYZ"	Submission sponsor name.
SourceSystem	Optional	Text	The name of the application that generated the Dataset-XML file.
SourceSystemVersion	Optional	Text	The version of the "SourceSystem" above.
data: DatasetXMLVersion	Required	"1.0.0"	The version of the Dataset-XML standard.

5.3.3 ReferenceData Element

The ReferenceData element contains non-subject data for a single dataset defined in the Define-XML document. Examples include the SDTM Trial Elements (TE) or Trial Inclusion/Exclusion (TI) domain datasets.

Element Name:	ReferenceData
Element XPath:	/ODM/ReferenceData
Element Textual Value:	<i>None</i>
Usage:	<u>Requirement:</u> Optional <u>Cardinality:</u> Zero or One <u>Other Information:</u> Contains ItemGroupData elements for non-subject data domains.
Attributes:	StudyOID, MetaDataVersionOID
Child Elements:	ItemGroupData

Attribute	Usage	Allowable Values	Description
StudyOID	Required	Text	<p>The unique ID of the Study. See the ODM specification section 2.11 for OID considerations.</p> <p><u>Business Rule:</u> The StudyOID must match the OID for the Study element in the corresponding Define-XML document.</p>
MetaDataVersionOID	Required	Text	<p>Unique ID for the MetaDataVersion that matches the corresponding MetaDataVersion OID in the <i>define.xml</i> file. See the ODM specification section 2.11 for OID considerations.</p>

5.3.4 ItemGroupData Element

The ItemGroupData element contains dataset data for an item group or record. Each ItemGroupData element contains a record in a single dataset within either the ClinicalData or ReferenceData element.

Element Name:	ItemGroupData
Element XPath:	/ODM/ReferenceData/ItemGroupData /ODM/ClinicalData/ItemGroupData
Element Textual Value:	<i>None</i>
Usage:	<u>Requirement:</u> Optional <u>Cardinality:</u> Zero or More <u>Other Information:</u> Contains the Items that form an item group or record. The ItemGroupData element exists as ReferenceData or ClinicalData making it optional within each element.

Attributes:	ItemGroupOID, data:ItemGroupDataSeq
Child Elements:	ItemData

Attribute	Usage	Allowable Values	Description
ItemGroupOID	Required	Text	<p>Unique ID for the ItemGroupData (dataset).</p> <p><u>Business Rule:</u> A ItemGroupDef element with the same OID must have been provided with the metadata in the corresponding <i>define.xml</i>.</p> <p>See the ODM specification section 2.11 for OID considerations.</p>
data:ItemGroupData Seq	Required	Integer	<p>Unique sequence # for each ItemGroupData (record in the dataset).</p> <p>It doesn't have any other meaning than the sequence in which the items were saved and exchanged for each ItemGroupDef. It is equivalent to the observation # in a dataset.</p> <p>Note that it doesn't have the same meaning as variables --SEQ in the SDTM context.</p> <p>It would be useful as a reference to Dataset-XML validators in reporting validation issues.</p>

5.3.5 ItemData Element

The ItemData element contains the value for a specific variable within an item group or record. Each data point in a given dataset exists in ItemData.

Element Name:	ItemData
Element XPath:	/ODM/ReferenceData/ItemGroupData/ItemData /ODM/ClinicalData/ItemGroupData/ItemData
Element Textual Value:	<i>None</i>
Usage:	<u>Requirement:</u> Optional <u>Cardinality:</u> Zero or More <u>Other Information:</u> This element contains the data values within a dataset. Either ItemData elements may be used in a single file, but not both.
Attributes:	ItemOID, Value
Child Elements:	None

Attribute	Usage	Allowable Values	Description
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ItemOID	Required	Text	<p>Unique Identifier for the ItemDef containing the variable metadata.</p> <p>ItemOIDs are required to be unique within the containing ItemDataGroup.</p> <p>Business Rule: An ItemDef element with the same OID must be in the corresponding define.xml.</p> <p>See the section 2.1.1 in the ODM specification for OID considerations.</p>
Value	Optional	Text	The data collected for an item. This data is represented according to DataType attribute of the ItemDef.

5.3.6 ClinicalData Element

The ClinicalData element contains study subject data for a single dataset defined in the Define-XML document. This element contains an ItemGroupData element for a single dataset.

Element Name:	ClinicalData
Element XPath:	/ODM/ClinicalData
Element Textual Value:	<i>None</i>
Usage:	<u>Requirement:</u> Optional <u>Cardinality:</u> Zero or One <u>Other Information:</u> Contains ItemGroupData elements for clinical data across multiple subjects.
Attributes:	StudyOID, MetaDataVersionOID
Child Elements:	ItemGroupData

Attribute	Usage	Allowable Values	Description
StudyOID	Required	Text	<p>The unique ID of the Study. See the ODM specification section 2.11 for OID considerations.</p> <p>Business Rule: The StudyOID must match the OID for the Study element in the corresponding Define-XML document.</p>

MetaDataVersionOID	Required	Text	<p>Unique ID for the MetaDataVersion.</p> <p><u>Business Rule:</u> The MetaDataVersionOID must match the OID for the MetaDataVersion element in the corresponding Define-XML document.</p> <p>See the ODM specification section 2.11 for OID considerations.</p>
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6 Acknowledgments

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Kevin Burges, Formedix	Jozef Aerts, XML4Pharma
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Veena Nataraj, Shire	Vojtech Huser, NIH
Priscilla Gathoni, Novartis	Yoshiteru CHIBA, UMINCenter, Japan

7 ODM Changes and Extensions Supporting Dataset-XML

Element / Attribute	Description
ODM/@data:DatasetXMLVersion	An extension attribute to capture the version of the Dataset-XML standard has been added as part of the Dataset-XML ODM extension.
ClinicalData/ItemGroupData	Allow the ItemGroupData element as a child of the ClinicalData element.
ItemGroupData/@data:ItemGroupDataSeq	Unique sequence # for each ItemGroupData (record in the dataset) has been added as part of the Dataset-XML ODM extension.

8 Appendices

8.1 Appendix A: XML Schema

The examples in this document are included in XML files as part of the Dataset-XML 1.0 publication. These XML files reference (directly or indirectly) the following schema files:

Dataset-XML schema	schema/cdisc-dataset-1.0.0/dataset1-0-0.xsd schema/cdisc-dataset-1.0.0/dataset-extension.xsd schema/cdisc-dataset-1.0.0/dataset-ns.xsd
DefineXML schema	schema/cdisc-define-2.0/define2-0-0.xsd schema/cdisc-define-2.0/define-extension.xsd schema/cdisc-define-2.0/define-ns.xsd
ODM 1-3-2 Schema	schema/cdisc-odm-1.3.2/ODM1-3-2.xsd schema/cdisc-odm-1.3.2/ODM1-3-2-foundation.xsd schema/cdisc-odm-1.3.2/xlink.xsd schema/cdisc-odm-1.3.2/xml.xsd schema/cdisc-odm-1.3.2/xmldsig-core-schema.xsd

8.2 Appendix B: Representations and Warranties, Limitations of Liability, and Disclaimers

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