Operational Data Model Version 1.2 Draft
Changes since Version 1.1

Revision History

Date	Revision	Description	Author
8-July-2003	1.0	Final	Sally Cassells

Introduction to Version 1.2

Version 1.2 of the CDISC Operational Data Model (ODM) is being released to industry for implementation and comment. This version introduces the XML schema representation of the model and includes several enhancements. These changes were driven by feedback from the CDISC Discussion Forum, the ODM Testing Task Force, and the ODM Team.

ODM Version 1.2 extends the functionality of ODM Version 1.1. Several elements and attributes have been added, but none have been removed. Elements and attributes that are present in both versions have the same interpretations. Version 1.2 has been designed to be compatible with Version 1.1, however, there are two ways in which an ODM 1.1 file will differ from an ODM 1.2 file:

1. An ODM 1.1 file will reference the ODM 1.1 DTD, while an ODM 1.2 file will reference the ODM 1.2 Schema (or DTD).
2. ODM 1.1 files can have certain date/time values that violate the ISO 8601 and XML Schema standards. ODM 1.2 files cannot. (Applications that read ODM files are urged to be forgiving on this point.)

Note change in DateTime format support: Version 1.1 used a non-standard method of indicating an unknown TimeZone. In Version 1.2, if the Time Zone for a DateTime is unknown, no offset is provided. The updated use is in accordance with ISO 8601.

Note: It is straightforward to use an XSL preprocessor to transform an ODM 1.1 file into a semantically equivalent ODM 1.2 file.

This document provides a summary of the changes between ODM Version 1.1 and Version 1.2.

In ODM 1.2, a few elements and attributes have been labeled as *deprecated*. This means that that element or attribute is still legal, but that its use is discouraged. Deprecated features may be removed in some future version of this standard. The list of elements or attributes that are deprecated in ODM 1.2 appears in the table below:

ItemGroupDef	Role Attribute	Intended to support an earlier version of the CDISC SDM model. No longer needed.
ItemDef	Role Element	Deprecated in favor of the new Role attribute on the Item Ref element
CryptoBindingManifest	Sub-element of Signature	Not usable as defined in version 1.1.

New Features in ODM Version 1.2

Digital Signatures

Digital signatures can now be used to provide tamper-proofing for ODM XML documents. CDISC has adopted the W3C XML Signature standard. See the W3C web site (www.w3.org/TR/xmldsig-core) for complete information about the ds:Signature element and it's sub-elements. The addition of a ds:Signature element to an ODM file ensures that modifications to the file contents can be detected. The addition of the ds:Signature element has no affect on the Signature element already in the ODM model.

Associations

The Associations element provides a mechanism for documenting links between clinical data records. The clinical data records linked by an Associations element may be in different Study Events, Forms or ItemGroups. The Annotation sub-element should be used to capture the significance of the association.

New Attributes for ODM Root Element

Several new attributes have been added to the ODM root element. These are:

ODMVersion	Identifies the CDISC ODM version used to generate this transfer or archive file. Default is 1.1 in order to provide backward compatibility for ODM V1.1 files.
Originator	Identifies the organization that generated the ODM file.
SourceSystem	Identifies the computer system used by the Originator to generate this ODM file.
SourceSystemVersion	Identifies the version of the computer system used by the Originator to generate this ODM file.

Imputation Method

An element ImputationMethod has been added as a sub-element of MetaDataVersion. It is designed to contain an algorithm description or program code fragment used to impute a clinical data value. If a program code fragment is provided it should provide a comment to identify the programming language.

MetaData Mappings

The Alias sub-element of an ItemGroupDef or ItemDef is used to map an ItemGroup or Item's Name attribute to another naming system. This may be useful when transmitting clinical data between systems when the relational structure in the sending system is not

the same as the relational structure in the receiving system. The Context attribute should be used to identify the application in which the Alias is used.

Item Roles

In earlier versions of the ODM, information about an ItemRole was stored in the Role sub-element of the ItemDef. However, an Item may be used in more than one ItemGroup within a study – each time with a different role. Better standardization can be achieved by using the Role attribute of the ItemRef element to hold Item Role information.

Audit Records

To provide better traceability and documentation of changes to clinical data, two new attributes, **EditPoint** and **UsedImputationMethod**, are provided. The **EditPoint** attribute identifies the stage in the clinical data collection process when the data change was made. The Used**ImputationMethod** attribute is used to indicate when the data change is the result of a derivation or imputation.

XML Schema

ODM Version 1.2 is provided both as an XML schema and as a DTD (Document Type Definition). Because the Schema captures more of the syntactic constraints of the model, it should be considered definitive. The DTD is provided for informational purposes and to provide backward compatibility with Version 1.1.

How to Comment on ODM V1.2

CDISC welcomes all comments on this version of the ODM. Please submit comments via CDISC's Public Discussion Forum.