



Introduction to the CDISC Operational Data Model

Version 1.1 (Final)

Purpose

The CDISC ODM 1.1 is being released to industry for implementation and comment. ODM 1.1 is intended to significantly increase the usability and functionality of the ODM Version 1.0 DTD. The Final version incorporates a number of changes and improvements that were identified during the comment period.

History

CDISC ODM 1.0 was released in October 2000, and has been used by several early adopters. ODM 1.0 was released along with a list of known issues and limitations, and further feedback has been collected since the time of its original release. Additional feedback was collected as a result of a live demonstration of ODM 1.0 conducted by more than twenty companies at the Drug Information Association's 2001 annual meeting in July 2001.

ODM 1.1 Draft, released in November 2001, addressed several of these issues and feedback points. For example, ODM 1.0 had insufficient support for audit trail representation, incremental transfers, complex visit representations, changes to key data values and vendor extensions. In addition, the CDISC LAB team requested specific features necessary to support the transfer of electronic lab data.

ODM 1.1 Final, first released in April 2002, includes a number of improvements to address issues that were identified during the comment period, which extended through February 2002. These changes, along with their source and rationale, are documented in a separate document, Release Notes for Version 1.1.

Structure and components of this release

The ODM 1.1 release consists of several files:

- a. An introduction (this document, ODMIntroductionV1-1Final.htm)
- b. An Overview document, which contains background and context (ODMOverviewV1-1.pdf)
- c. The ODM 1.1 Specification (ODM1-1Specification.html)
- d. The ODM DTD presented in two formats: ODMDraftv1-1.dtd includes parameters for vendor extensions; ODMDraftv1-1nx.dtd is the same DTD without vendor extension parameters, to improve readability
- e. An evolving set of examples and white papers
- f. An evolving collection of tools and utilities, including an XSL based viewer of ODM 1.1 data and metadata (provided on a free 'click license' basis from PHT Corporation) and a tool to allow validation of a vendor-extended DTD against the CDISC ODM 1.1 standard model.

The ODM 1.1 Specification includes both syntactical and semantic information critical to the understanding and application of the model. This Specification, along with the Introduction, Overview and DTDs are available in a zip file at <http://www.cdisc.org/std/ODM/V1-1/ODMv1-1-0.zip>.

Additional examples, white papers and tools will be provided incrementally after the initial posting of the model.

Details of functionality supported in this release

- Ability to address changes to key data values
- Expanded transaction support for partial or incremental transfers and archives
- Expanded metadata descriptions of more complex event structures
- Support for including multiple studies and reusable metadata in one file
- Support for depicting non-patient reference data
- Support for vendor extensibility
- Increased compatibility with the CDISC Submissions Data Model
- Increase support for archiving of clinical data and metadata

- Elimination of support for the flat representation of clinical data included in version 1.0
- Corrections to numerous bugs including those related to timezones, locales and signatures
- Changes to the order of elements.
- Changes to element names and attributes, including the ItemData element.

How to comment on this release

Please register all comments by using the CDISC Discussions Facility, <http://www.cdisc.org/forum/default.asp?page=1&b=1> in the folder titled “Operational Data Model Version 1.1 DTD Comments”.