10.1 CDISC ODM - General Issues

CDISC defines its Operational Data Model, version 1.3, as a vendor neutral, platform independent format for interchange and archive of clinical trials data. The model includes the clinical data along with its associated metadata, administrative data, reference data and audit information. All of the information that needs to be shared among different software systems during the setup, operation, analysis, submission or for long term retention as part of an archive is included in the model.

An XML document must meet certain basic criteria to be considered conformant to the ODM standard. These are briefly discussed below:

Approved for publication by Cal Collins. Signed on 2014-04-02 2:54PM

Not valid unless obtained from the OpenClinica document management system on the day of use.

10.1.1 Syntatic Constraints

The syntactic constraints defined by the ODM standard are

1. The ODM file must be a well-formed XML file. See the XML standard for details.

2. The ODM file must conform to the XML Namespace standard. See the XML Namespace standard for details.

3. The ODM file must contain only elements and attributes defined in the ODM standard schema or in a valid vendor extension schema, and must satisfy the rules about element nesting and the formats of attribute values and element bodies.

4. The ODM file must contain a prolog and a single (top-level) ODM element.

5. The namespace for version 1.3 of the ODM is http://www.cdisc.org/ns/odm/v1.3.

OpenClinica ODM Exports from the Extract Data module meets these constraints.

Currently, the ODM study definition file (available from the View Study page at the URL /DownloadStudyMetadata?studyId=#) does not meet these requirements for the following reasons:

1. The file generated from the View Study page is only a fragment of XML, and does not contain the initial tag which defines the character set and version, i.e. <?xml version="1.0" encoding="UTF-8"?>.
2. The file generated does not contain references to any XML Namespaces, including the namespace for version 1.3 of the ODM itself.
3. The file generated does contain elements defined in the ODM standard schema, but lacks the single top-level ODM element.
4. The files suffix is txt instead of xml.

OpenClinica ODM Data Import meets the above constraints, but note that OpenClinica parses everything within the ClinicalData element only, and it does not read anything in the Study element, and, as such, cannot import Study metadata at this time.

10.1.2 System Conformity

A computing system that processes information in ODM format can claim conformance to this standard only if it obeys the following rules.

1. Generated ODM files must satisfy all the correctness rules in the standard, both syntactic and semantic.

2. A receiving system must be able to read any ODM file that satisfies all the correctness rules in this standard, both syntactic and semantic.

3. ODM files must validate against the ODM schema for the ODM version indicated in the ODM root element.

4. Information included in generated ODM files must be accurate according to the rules of this standard as defined in this specification.

5. A receiving system must interpret information read from an ODM file accurately according to the rules of this standard as defined in this specification.

6. Generated ODM files need not include information that is not normally handled or stored by the generating system.

7. A receiving system may selectively ignore information read from an ODM file if that information is not normally handled or stored by the receiving system.

8. A receiving system may constrain the range of data values, keys, names, and so on, that it is capable of handling or storing.

9. Systems that receive ODM clinical data files but do not normally support one or more of the datatypes specified in section 2.14, should accept clinical data of the unsupported types as text.

10. All system limitations (rules 6 through 9) must be documented.

11. If conformity is dependent on certain modes or settings, this must also be documented.

OpenClinicas support for generated and received meets these constraints, including documentation of limitations (#10). The limitations are described in the Limitations section of this document.

10.1.3 Vendor Extensions

Requirements for Vendor extensions to the ODM model are:

1. The vendor must supply a XML Schema fully describing their extended ODM format.

2. Extended ODM files should reference the proper extension Schema.

3. The extension may add new XML elements and attributes, but may not render any standard

ODM elements or attributes obsolete. Vendor extensions cannot be used for information that is normally expressed using other ODM elements.

4. All new element and attribute names must use distinct XML namespaces to insure that there are no naming conflicts with other vendor extensions.

5. Removing all vendor extensions from an extended ODM file must result in a meaningful and accurate standard ODM file.

6. Vendors should be able to produce ODM files free of any vendor extensions upon request.

OpenClinica meets these requirements in its use of vendor extensions.