

Tools for working with CDISC ODM, CDISC Lab and define.xml Standards

What is available ?

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An overview of tools that ...

- **Are publicly available**
- **Directly act on / work with ODM, Lab or CRT-DDS files**
- **Have been designed starting from the standard**
- **Concentrating on Europe**

CDM Systems

- Many CDMS systems can now export in ODM format
- Some can import ODM format ...
- Some have been designed with the ODM in mind
 - Easier handling of data
 - ODM Conformity guaranteed
 - Faster (?)

CDM Systems build on basis of the ODM

- **XTrial** (CRO24)
- **Express** (Formedix)
- Open Source: **Visitrial**

Study Design Tools

- **Origin** (Formedix)
- **XC Designer** (DataLabs)
- **Others from Pharma companies ?**

Conformity and Validation Tools

- **ODMChecker** (XML4Pharma)
 - Java based
 - Free for CDISC members
 - Small fee for non-members
 - Extensible (e.g. as server application)
- **ODMConform** (Assero)
 - MS based
 - Small fee

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Checking ODM file C:\CDISC_ODM_Checker_testfiles\ODM1.2\CTChicago_XSchema_not_conform.xml

Results from checking the CDISC ODM Document

Checking ODM file C:\CDISC_ODM_Checker_testfiles\ODM1.2\CTChicago_XSchema_not_conform.xml

Level 1 ERROR when reaching line 3
Incorrect value for attribute
Found : "Absent"
The attribute should have one from the the following list of values :
All, Metadata, AdminData, ReferenceData, AllClinicalData, SingleSite, SingleSubject

Level 1 ERROR when reaching line 3
The value "Absent" of attribute "Granularity" on element "ODM" is not valid with respect to its type, "Granularity".

Level 1 ERROR when reaching line 69
The value "AExxxxxxxxxxxx" of attribute "SASDatasetName" on element "ItemGroupDef" is not valid with respect to its type, "sasName".
The attribute length is more than 8 characters or contains invalid characters.

Level 2 ERROR when reaching line 202
Length attribute of ItemDef element with OID "TT.ABNORM" is missing
Length attribute is required when the DataType attribute has the value "integer" or "float" or "text"
The system will not be able to check ItemData elements with ItemOID="TT.ABNORM" for length correctness of the Value attribute

Level 1 ERROR when reaching line 202
The value "ABNORM SDS Variable Name" of attribute "SDSVarName" on element "ItemDef" is not valid with respect to its type, "sasName".
The attribute length is more than 8 characters or contains invalid characters.

Level 1 ERROR when reaching line 202
The value "ABNORMMMMMMM" of attribute "SASFieldName" on element "ItemDef" is not valid with respect to its type, "sasName".
The attribute length is more than 8 characters or contains invalid characters.

Level 2 WARNING when reaching line 219
Element MeasurementUnitRef has an unregistered value for the MeasurementUnitOID attribute
MeasurementUnitOID attribute value "PU.DPML" was not previously registered in a MeasurementUnit element using OID attribute
MeasurementUnit elements can be found under the BasicDefinitions element

Level 1 ERROR when reaching line 235
The value "A" of attribute "Length" on element "ItemDef" is not valid with respect to its type, "integer".
The attribute value must be a positive integer

Level 2 ERROR when reaching line 244
Length attribute of ItemDef element with OID "TT.AEENDAY" is missing
Length attribute is required when the DataType attribute has the value "integer" or "float" or "text"
The system will not be able to check ItemData elements with ItemOID="TT.AEENDAY" for length correctness of the Value attribute

Level 1 ERROR when reaching line 277
```

Viewers

- **PHT CDISC Viewer**
 - Nice ODM Viewer
 - Supports ODM 1.1 only
 - obsolete
- **ODMViewer (XML4Pharma)**
 - Similar functionality
 - Allows visualization of subsets
 - Easily extensible
 - Small fee

Demo at end of presentation

Test Suites

- **ODMTest (Assero)**
 - Large set of ODM files
 - With documentation:
 - What is there
 - Expected results
 - Currently undergoing final development

ODM – SAS Interface

- **SAS Proc CDISC**
 - Included from SAS v.9
 - Add-on for SAS 8.2
 - Downloadable from SAS website
- **Tekoa Technology Toolkit (Zurich BioStatistics)**
 - Import / export
 - Free for CDISC members

Other tools for ODM

(from XML4Pharma)

- **Automatic transformation to e-CRFs**
 - In XForms format, so:
 - Using W3C standard
 - Usable in browser, PDA, cell phone ...
- **Web Services**: automatic exchange between sponsor and CRO
- **Reporting tool**: transformation to **PDF reports**

Other tools for ODM

(from XML4Pharma)

- **Electronic Signatures** in ODM: Signing and Validation tool
- **Native XML database** with > 3000 e-CRFs in ODM format
- Try it out yourself at www.XML4PharmaServer.com

Tools for working with the CDISC Lab Standard

The CDISC LabChecker (XML4Pharma)

- Server application developed for **Gereq**
- Allows conformity check of all incoming CDISC Lab files in XML format
- Web based
- 21 CFR Part 11 compliant
- Simplified versions available online at www.XML4PharmaServer.com
 - For Lab files (base) in ASCII format (bar-delimited)
 - For Lab files (base) in XML format

[Demo at end of presentation](#)

The Lab ASCII to Lab XML Converter (XML4Pharma)

- XML implementation of Lab standard becomes important
- Tool to convert between ASCII and XML became necessary
- Online available at www.XML4PharmaServer.com

Tools for working with the define.xml Standard

Considerations

Tools for working with define.xml standard

Considerations

- The standard is very young ... but important
- Comes already with a stylesheet for HTML presentation and inspection
- Inventarization of needs and requirements
- Plans:
 - Extend ODMChecker for use with define.xml
 - ? ? ?

Demos

- ODMViewer
- CDISCLabChecker

