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

What is available ?

Jozef Aerts
XML4Pharma

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

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**