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Happy New Year

XML4Pharma wishes all its customers, colleagues and contacts a happy and healthy 2005 ! Also this year we will deliver you news about what is happening in pharmaceutical XML and IT world, like news about new CDISC standards, new tools for working with it, and many other interesting articles.

Eight tools for working with CDISC standards now available online

New free tools for working with the CDISC set of standards have recently been added to the our application server. This brings the number of online available tools to eight. The new tools are CDISC Lab Checkers (one for the ASCII implementation and one for the XML implementation) and a tool for electronically signing ODM files (but also other XML files), and to verify the electronic signature of an ODM file.
The **CDISC Lab XML Checker** is a new tool for checking the validity of a CDISC Lab file (XML format) against the standard. This validity checking goes far beyond a simple checking against the XML-Schema: also rules of the standard that could not be described in the Schema are checked for. As such the CDISC Lab XML Checker is the first in its kind. One of our customers already integrated an extended version of our checker into its own systems and processes.
The second new tool is the **CDISC Lab ASCII Checker**: it is similar to the XML Checker, but now accepts a CDISC Lab file in ASCII format.
The third new tool allows to **sign an ODM file with an electronic signature**. Also signed files can be validated using this tool. Signing is done using the new W3C standard for electronic signatures, named XML-Signature. This standard not only gurantees document integrity (i.e. if only 1 character in the document is changed, the signature automatically becomes invalid), but also allows signer authentication (e.g. using a X509 certificate). So XML-Signature is the best way to add e-signatures to all kinds of XML documents, like e-CRFs, CDISC ODM files and Lab files.
More tools are currently under development. All these tools are **freely usable online**. The address is: **www.XML4PharmaServer.com**

Adobe PDF forms and XForms: competitors or allies ?

There are currently two main technologies available for electronic forms like e-CRFs: Adobe has its **PDF forms**, and there is the new W3C standard for electronic forms: **XForms**. Apparently, it looks as these are competing technologies, but this is not completely so. At the same advantage and disadvantage, XForms completely separate data from presention. Therefore e-CRFs in XForms format can be automatically created from e.g. CDISC ODM files with a

Study definition. The disadvantage is, that for a nice presentation, the developer still needs to write a set of stylesheets for presentation. Adobe PDF Forms, however, can be easily shaped to a nice and functional presentation with easy-to-use tools like Acrobat Professional, but the forms themselves (with all the logic), need to be introduced more or less "by hand". There is however now Adobe's **XML/PDF designer**. This tool allows to combine all the advantages of XForms (like automatic generation) with the use of PDF forms and documents: PDF forms and XForms can be used interchangeably in an XML workflow. The XML/PDF designer can export PDF forms as well as in classic PDF format, as in XDP (XML Data package) format. An XDP file is a portable XML file that contains XML form data, XML form templates, PDF documents and other XML information. Especially for companies that already rely on Adobe technology for e-CRFs, the incorporation of automatically generated e-CRFs (in XForms) into PDF electronic documents, can be a very interesting option, both saving a lot of time and money.

News from CDISC: the define.xml standard, and a new ODM extension mechanism

A draft of the CRT-DDS standard (better known as defime.xml) was published by CDISC in August 2004. Both the define and ODM teams have been working hard on the new standard since then, and on its technical implementation. As a result, the final specification will soon be published on the CDISC web site, together with two XML-Schema sets, one "hard-coded" and one based on a new ODM (vendor) extension mechanism, developed by Anthony Friebel of the SAS Institute.
The new ODM extension mechanism now allows to develop ODM extensions (like the define.xml) in such a way that the extensions can be validated using standard tools and parsers (with the old extension mechanism, validation required custom software development).
Team discussions about this new mechanism were heavy, as the current version of a major tool, XMLSpy, contains a bug (due to a different interpretation of the W3C standard for XML-Schema) so that the new extension mechanism is not supported. XML4Pharma submitted this bug to Altova (the maker of XMLSpy), and after some discussions, Altova admitted it is a bug, and promised to correct it in their SP2 release, which is foreseen for February 2005.
Using this new extension mechanism, it is e.g. also possible to have as well define.xml data, classic ODM data, together with CDISC Lab data, into a single file, and to validate the result. A set of example files of this can be obtained upon request.

Oracle declares war to native-XML databases ?

The latest issue of Oracle magazine (Jan.2005) contains some interesting articles related to XML and Java: one of the articles is about the smooth transformation from Oracle Forms to Java-based forms (4 years ago, when I told my colleagues they should start learning Java instead of Forms, they laughed at me). Others are about how to export relational data as XML (teached in our courses), about XML-Signature (see before) and a fourth is about XQuery, the new standard for quering both relational and native XML databases. At the end of the article **the author states that XQuery means the end of native XML databases**.
What she forgets is that one of the advantages of native XML databases is that no mapping to relational tables is necessary. As such, we believe that native XML databases have their place, especially when incoming data are already in XML (like e-CRFs). Of course, also Oracle databases allow to store XML documents natively, so that even Oracle databases act as native XML databases.