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A new tool: CDISC Lab ASCII to Lab XML Converter

For Central Labs, the easiest way to provide CDISC Lab data is to use the ASCII implementation of the standard. For the receiving party however, this has the disadvantage that the received data is difficult to validate, in some cases difficult to store in databases, and difficult to transform into ODM format.

Therefore we developed a "CDISC Lab ASCII to Lab XML Converter". The tool converts a Lab file in bar-delimited ASCII format into a Lab XML file that fully conforms to the XML-Schema.

This new tool is now available as a standalone application against a small fee (CDISC members get a discount), but can also be freely used on our application server (see next section)

For more information about this tool, visit our web site at www.XML4Pharma.com and click on "**tools for working with the CDISC ODM and Lab Standards**".

New applications on our demo application server

We recently have made a few changes to our application server (www.XML4PharmaServer.com). First of all, we deployed the "**CDISC Lab ASCII to Lab XML Converter**" as a web application. This means that users of our application server can simply submit a CDISC Lab file in ASCII format, and within seconds, get the result in CDISC Lab XML.

As we care about your privacy: nor the submitted ASCII nor the generated XML is ever stored on our server.

Secondly, we changed the application demonstrating the use of **native XML databases**. Our demo database contains a set of over 3000 e-CRFs in CDISC ODM format. The change is that we now migrated to the eXist database, which has XPath2 capabilities. This enables for example to perform date and time comparisons. For example, using an XPath2 expression, all e-CRFs with a DateTimeStamp within in a certain time span can be retrieved.
Furthermore we considerably extended the included **XPath tutorial**, learning users which XPath expressions can be used to query the database with e-CRFs.

As always, the use of our demo application server is for free. Only a one-time registration is necessary.

The final version of the new CDISC define.xml standard

The final version of a new standard, the "Case Report Tabulation Data Definition Specification" (CRT-DDS), better known as "define.xml" (as it replaces the define.pdf FDA submission document) will now soon be published on the CDISC website.
During the team meeting at the DIA conference in Washington in October, the last issues (about the XML-Schema) were resolved.
At the DIA meeting, representatives of the FDA stated (unofficially of course) that the new standard will enable them to treat submissions considerable faster when the CRT data definitions come in define.xml format.
The CRT-DDS is being implemented as

an extension of the CDISC ODM standard, i.e. a define.xml file just looks like a CDISC ODM file with some extra elements and attributes (using the prefix def:).
We will also soon start on extending the **CDISC ODM Checker** so that it can check the validity and consistency of define.xml files. This will enable pharma companies to check these define.xml files on correctness and consistency in a very user-friendly way before sending them to the regulatory authorities.

The CDISC ODM and Lab Implementation workshop

On behalf of CDISC, we gave a successful "CDISC ODM and Lab Implementation Workshop" in Munich at the end of September. Attendees of the workshop were about 50% from technology companies (i.e. software and systems vendors) and bout 50% from pharma companies. Attendees learned how to export/import XML data from and into relational databases and CDMSs, setting up databases from information in the ODM, how to incorporate Lab data into ODM files, how to automatically create e-CRFs from the ODM Study definition, and how to check the validity of ODM files. Furthermore there were session about the relation between ODM and SDS, electronic signatures in XML, native XML databases and Web Services for exchange of clinical data between sponsor and CRO.

If you would like to have a similar course or workshop organized for your company at your location, please contact us. We can then tailor the workshop to the needs of your company. More information is also available on our website.

XML4Pharma at the DIA e-Clinical Interchange in Washington

We attended the first two days of the joint DIA – CDISC conference in Washington in October. At the first day, we gave a CDISC XML course. A bit surprising, a large part of the attendees were SAS programmers, eagerly wanting to gather XML skills. This shows that the use of XML in clinical data management departments becomes now generally accepted.
The second day was devoted to a CDISC joint teams meeting. From this it became clear that integration between the different standards will become CDISCs highest priority in 2005. We were encouraged to exchange members between teams, so that teams can not work as separate islands anymore.

All together, this was a very successful day, also from the social side, as it enabled to finally meet all those great volunteers face-to-face when only knowing them from teleconferences and e-mails before.

Best Practices: Web-based CRF saves Wellspring 30 Percent over Paper Records

Bio-IT world recently published an interesting article about how Wellspring, a U.S. based pharma company, implemented web-based CRFs for evaluating a new drug in clinical studies. Immediate savings for not having to distribute software to the locations was 30%. The system included an automatic alert system for dosing errors, by this reducing protocol violations (which cost about $3000 per violation). Unexpectedly, the FDA required an interim analysis. With paper based CRFs, this would have retarded the study for at least an extra half year. Overall savings (for a first trial) were estimated to be over $100,000. This does not include yet the savings in time (shorter time-to-market).