CDISC ODM & Lab Implementation workshop

CDISC and XML4Pharma organize a full-day workshop on implementing the CDISC XML-based standards. The workshop learns the participants how to set up tools and systems for working with the CDISC ODM and Lab standards. The workshop contains a lot of demos, for which some of them, the source code will be made available. The workshop also learns the participants the principles of XSL-transformations, which is essential for being able to transform XML documents and exchange them between applications. The workshop is especially interesting for project managers, senior developers, clinical data specialists, essentially all those who are involved in the implementation of CDISC standards in their organization.

Some of the topics that will be treated:
- import/export from DB and CDMS
- automated database setup
- relation between ODM and SDS
- automatic generation of e-CRFs
- electronic signatures in XML
- web services
- XML-databases
- and much much more.

The full program can be found at:

www.XML4Pharma.com/CDISC_Implementation_Workshop.html

The workshop will take place on September 30th, at CRO24 in Munich.

Registration information can soon be found on the CDISC Education website at: http://www.cdisc.org/education/

LIMS and XML

Scientific Computing & Instrumentation (www.scimag.com) has now published its yearly overview of Laboratory Information Systems that are available on the market. For the first time, the magazine also asked the manufacturers about XML-import/export and about the possibility of exchange of data with other systems using web services.

The results are very interesting: of the 66 listed systems, 66% have a web interface available. 73% claims to be able to read and write XML, and 24% can exchange data with other systems using a web service.

Where about a year ago, the number of systems that claimed to read and write data in XML format was still very limited, now only 1 in 4 does not have this capability. Also the use of web services is rapidly growing. Already 1 in 4 claims to have it available, with a large number of other saying they will have it available in the next release.

New applications on the XML4Pharma application server !

The XML4Pharma application Server (www.XML4PharmaServer.com) is now up and running for about a month. A good number of users has tried out the available tools and has given us very positive response. Recently we also added a **web service** to the application server. It demonstrates how

automated exchange of data between a sponsor and CRO can be accomplished over the internet, even though both have completely different systems. A Perl-based client (source code) is made available to first-time users. Users with some more knowledge about web services can download the WSDL, and develop their own software or integrate the web service into their own systems. In near future we will also provide a Java application that can be used as a client.

The XML4Pharma Application server is freely available to anyone wanting to try out one of these modern technologies. Other tools are currently being developed that also will be made available on the application server.

The ODM Checker v.0.5 is now available

A new version of our tool, the CDISC ODM Checker (v.0.5) is now available. The ODM checker checks ODM files for validity and integrity.

The new version now also checks ODM v.1.2 files, either using the new XML-Schema, or using the classic DTD.

Furthermore, there are many improvements, and more options available.

The CDISC ODM Checker is freely available for CDISC members. If you work for a company that is a CDISC member (the full list can be found at the CDISC website), send us a mail with your credentials, and we will make a copy of this powerful software available for downlaod.

A version that can be deployed on a central application server is currently in development.

Oracle Clinical and CDISC XML

We have now almost completed our inventarization of tools for letting Oracle Clinical and CDISC XML work together.
If you are interested in the results of our investigations, please give us a phone call or an e-mail.

The XML4Pharma application server and automatic creation of e-CRFs

The most successful application on our new application server (**www.XML4PharmaServer.com**) is surely the application for the automatic creation of e-CRFs., from CDISC ODM files with a Study definition. For those not having used this application, a short explanation about what this application does, and how it works:
The user chooses an ODM file from his/her own computer, and submits this to the server. The application then generates a set of e-CRFs in XForms format from the submitted ODM file. For those having the FormsPlayer plugin (an IE plugin to work with XForms – **www.FormsPlayer.com**), the XForms can be tested directly using IE (having the advantage that validation is done by the client itself – so: faster). For those who do not have the FormsPlayer plugin installed (or do not want to use a plugin), we provide a server-side implementation of XForms (Chiba). With this server-side implementation the submitted XForms is send back to the user if one or more fields contain invalid data.

DOB	19570507	*
HT	19a	*	Must be a floating point number.
HTUNITS	cm	*
RACE	Caucasian	*
SEX	Male ▼	*
WT	84	*
WTUNITS	kg	*

If however, all the submitted data is valid, the application shows the XML structure that is being send to the server. In a real production environment of course, the produced XML will be stored or directly transformed into CDISC ODM format.

Native XML Databases

Another application that is available on our application server is a native XML database storing about 3000 e-CRFs in CDISC ODM format. The database can be queried using XPath expressions. As XPath is rather different from SQL, we now also provide an XPath tutorial learning how to retrieve selected XML documents from the database.

XML4Pharma at the October DIA Meeting in Arlington

XML4Pharma has been invited to give an XML training at the DIA e-Clinical Interchange in October in Arlington (VA). This will also give us the opportunity to meet our US based customers in person during the meeting. So if you come to the DIA meeting, and you want to talk to us about CDISC implementation or other matters, let us know, and we will arrange for a personal meeting.

XML4Pharma is CDISC Registered Solutions Provider

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CDISC ODM and Lab Implementation Workshop
How to make the promises of XML-based CDISC standards true

September 30, 2004
Munich, Germany

Registrations soon to be accepted at:

www.CDISC.org/education/index.html