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The XML4Pharma Application server is now up and running !

The XML4Pharma application Server (www.XML4PharmaServer.com) is now up and running. At the moment it concentrates on demonstrating tools that can be used for working with the CDISC set of standards. Currently the following applications have been deployed:

- Automatic conversion of ODM Study data into e-CRFs. The e-CRFs are created in idiot-proof XForms, and can be directly used or downloaded from the website.
- A reporting tool: it takes an ODM file and transforms it into a PDF report
- A demo application showing the use of a native XML database and of XPath expressions. The database contains about 3000 e-CRFs in ODM format.

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

CDISC European Interchange

The first European CDISC Interchange took place last week in Brussels. Besides the one and a half day conference, there were also several workshops. XML4Pharma gave two workshops: the first was a basic XML course (using the CDISC ODM and Lab as working

examples), attended by 17 participants. The second workshop, given in cooperation with Dave Iberson-Hurst (Assero) was a Lab and ODM XML Implementation workshop. This workshop was attended by 28 participants. Both workshops had participants coming from small CRO up to big pharma: a good sign that the use of CDISC standards and XML is now generally accepted. Both workshops received very positive response. If you want us to give a similar workshop or training (tailored to your needs) at your company (as we did already in the past), do not hesitate to contact us.

Oracle Clinical and XML

At the European CDISC Interchange it again became clear: many pharma companies do not implement CDISC ODM and Lab as their CDMS Oracle Clinical does not have provisions for reading and writing XML data. There are however solutions for this problem. We are currently making an inventory of available tools for import/export of XML in Oracle Clinical. If you would like to know more about this, just give us a phone call or an e-mail.

Automatic creation of e-CRFs

One of the promises of using the CDISC set of standards is that it will save both time and money in clinical trials and provide cleaner data.

The use of the CDISC ODM to describe a study setup already allows the **automatic creation of SQL statements to set up a database** (see our website under Products for use with the CDISC ODM). We now also developed an application that reads the Study section of the CDISC ODM and **automatically creates a set of e-CRFs in XForms format** (see our previous newsletter or the website). **You can now try out this application using our application server** (located at www.XML4PharmaServer.com).

XForms have the great advantage that they can be made pretty **idiot proof** (thus improving data quality), that they are in principle device-independent (they can be deployed in a browser, on a PDA, on a mobile phone ...) and that they send their data back to the server in XML format (making it easy to store them in an XML-database or to store them in a CDISC ODM file).



If you have one or more ODM files with a Study set up, you are invited to try out our new application. Your privacy is guaranteed: submitted files are never stored on our server, and generated XForms are regularly deleted.

The XML4Pharma application server and automatic creation of e-CRFs

The application for automatic creation of e-CRFs, as implemented on our application server, works as follows: 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), 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.

A screenshot of a form with several fields: 'DOB' (19570507), 'HT' (19a), 'HTUNITS' (cm), 'RACE' (Caucasian), 'SEX' (Male), 'WT' (84), and 'WTUNITS' (kg). A red error message 'Must be a floating point number.' is displayed next to the 'HT' field.

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 also provide an XPath tutorial learning how to retrieve selected XML documents from the database.

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