

**Bimonthly newsletter of XML4Pharma, a subsidiary of
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XML4Pharma gives Web Services course at InfoTechPharma 2004

XML4Pharma has recently been hired to give a full-day course on Web Services at InfoTechPharma 2004, which will take place at the end of January in London.

The course will give the participants a jump start in the development of web services: **during the course, we will develop a basic web services system for the exchange of clinical data between sponsor and CRO.**

InfoTechPharma is the major European yearly event on IT in the pharma industry. More information about this event can be found at www.InfoTechPharma.com.

If you would like to have this or a similar course to be given at your location, please do not hesitate to contact us. More information about our courses, how they are set up, and pricing information can be found on our website at:

www.XML4Pharma.com/courses.html

CDISC releases ODM 1.2.

CDISC (the Clinical Data Interchange Standards Consortium) will now soon release the 1.2 version of the ODM (Operational Data Model), the XML-based standard for exchange of clinical data.

The major difference with the ODM version 1.1 is the availability of an XML Schema. This will make it easier than ever before to construct software for working with the ODM, to automate tasks like automatic database table creation, automatic e-CRF creation, validation of ODM XML files, etc... The ODM 1.2 is almost fully downward compatible with the 1.1 version. Companies wanting to transform ODM 1.1 files to the 1.2 version will easily be able to do so using an XSLT stylesheet.

XML4Pharma moving to Germany

My family and I recently moved to Singen, in the South of Germany. This is due to the occupation of my wife (she is a QA manager at a very large food company). This means that at the end of this year, Computer Chemistry Consultancy - XML4Pharma will move its official seat from Switzerland to Germany. Our new address in Germany will be: Schlossbergstrasse 20, 78224 Singen, Germany. The new telephone number is already listed in the heading of this newsletter.

CDISC-ODM Checker now available

We recently finished the production release of the CDISC ODM Checker. This software tool checks an ODM file (v.1.1) against the standard, and reports non-conformities in very well

understandable, non-specialist language. Checking is performed at two levels. The first level is checking against the DTD (Document Type Definition). The second level consists of a thorough check against the standard as described on the CDISC website.

Extremely useful is that the ODM Checker also checks the internal consistency of the ODM files. For example, it is checked whether individual items in a CRF really belong there, and whether the value given for an item is of the correct type (integer, float, date, string). If coded values are used, also checks are performed against the codelist.

The CDISC ODM Checker has many more features, which are well described on our website at:

www.XML4Pharma.com/CDISC_Products/

The website also contains a number of movies demonstrating the use of the software.

CDISC members can obtain the CDISC ODM Checker for free from the CDISC e-room, or directly from XML4Pharma, by simple e-mail request. The tool will also be made available in the “Members Only” section of the CDISC website in the near future.

XML implementation of the CDISC Lab Standard released

The CDISC Lab Team has now released the XML implementation of the Lab Standard.

We have performed a number of technical test on the provided XML Schema and a Lab XML example file. Our conclusion is that this XML implementation is very well suited for automated data exchange between labs

and their commissioners: the XML Schema has been very well developed and lets itself easily translate into Java classes and into database table templates.

With this XML implementation, the CDISC Lab Team has made a major step forward in enabling the integration and standardization of systems for the exchange of laboratory data.

XForms makes it to a W3C Recommendation

Very recently (October 14th), the World Wide Web Consortium (w3c) announced that XForms is now an official recommendation. XForms is the logical successor of HTML forms. One of the major disadvantages of classic HTML forms is that their content is difficult to evaluate. Therefore, in most cases, evaluation is done at the server, leading to increased browser-server traffic and to slow performance. Not so with XForms: XForms uses standard data types which are evaluated within the form. This enables to make web applications using XForms almost idiot proof. **As such, XForms can be a very good choice for developing web applications in clinical data interchange:** an investigator in a hospital typically will need only 1/3th of the time to fill in an XForm relative to using an HTML form. Furthermore, the number of errors is considerably reduced.

Very interesting is that XForms can be automatically generated from XML documents, such as the CDISC ODM.

The only disadvantage right now is that XForms still requires special browsers, but now that the final specification is published, this will probably change very soon.