

Bimonthly newsletter of XML4Pharma,  
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**CDISC ODM & Lab Implementation workshop: registration now open**

Registration is now open for the CDISC ODM and Lab implementation workshop that will be given by XML4Pharma on September, 30<sup>th</sup>. Full details about how to register are now available at:

[www.cdisc.org/education/sep30\\_2004.html](http://www.cdisc.org/education/sep30_2004.html). As the number of places is limited to 30, do not hesitate and subscribe now for this unique workshop.

This workshop learns the participants how to set up tools and systems for working with the CDISC ODM and Lab standards. It contains a lot of demos, for which some of them, the source code will be made available. Also the principals of XSL-transformations, which is essential for being able to transform XML documents and exchange them between applications, will be taught.

Some of the topics that will be treated:

- import/export from databases and Clinical Data Management Systems.
- automated database setup
- incorporation of Lab data into ODM
- relation between ODM and SDS
- automatic generation of e-CRFs
- electronic signatures in XML
- web services for exchange of data
- XML-databases
- and much much more.

The full program can be found at the CDISC website (under education) and at:

[www.XML4Pharma.com/CDISC\\_Implementation\\_Workshop.html](http://www.XML4Pharma.com/CDISC_Implementation_Workshop.html)

The workshop will be hosted by CRO24, at their location close to the central railway station of Munich.

**GAML is dead ! Long live AnIML !**

GAML, the “Generalized Analytical Markup Language”, for being able to exchange analytical data between analytical instruments, LIMS systems and other computerized systems in a vendor-neutral way, seems to have died in a silent way. Also the GAML website has been removed. GAML was originally proposed by Thermo Galactic (now Thermo Electron - Informatics) as a new XML-based standard. The fact that the “standard” was proposed by a single vendor, is probably the main reason why it was never enthusiastically supported by other vendors. When setting standards, it is most important that representatives of the whole industry are involved, communicating their expectations and giving input. This has obviously not been the case for GAML.

However, a new standard for exchanging analytical information has now being set up under the wings of ASTM, the American Society for Testing and Materials, which is of course a better guarantee for general acceptance. AnIML (Analytical Information Markup Language) is the name of this new standard. This time, many of the main vendors of analytical instruments and LIMS systems are involved, with regular meetings and presentations and discussions at conferences.

The website of AnIML can be found at: <http://animl.sourceforge.net/>

## **New standards from CDISC**

The CDISC organization is currently working hard on a number of new standards to be used in clinical research and in submission of clinical data. The SEND models (Standard for Exchange of Nonclinical Data) have now been published for public review on the CDISC website. SEND is currently focussing on toxicological data from animal studies. Just like the SDS, SEND is not an XML-based standard, but a set of guidelines for submissions of data to the FDA.

Also the Lab team has released a new draft (update) of the Reference Range Model of the Lab model.

Another new important standard that has been published for public review is the “Case Report Tabulation Data Definition Specification” (CRT-DDS). It should be regarded as the XML-version of the well-known “define.pdf”, so many people just call it “define.xml”. 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:).

XML4Pharma is currently involved in testing the XML-Schema and example files of this new standard. We also envisage to make an extension to the CDISC ODM Checker to check define.xml files, so that pharma companies can check these files on correctness and consistency in a very user-friendly way before sending them to the regulatory authorities.

## **Some improvements on the XML4Pharma application server**

We now have made some improvements to the XML4Pharma application Server (located at [www.XML4PharmaServer.com](http://www.XML4PharmaServer.com)). First of all, a Java client for the web services demo application (demoing

rapid exchange of ODM files between sponsor and CRO) can now be downloaded from the website and can be used to retrieve ODM files from our site. It comes with a user-friendly graphical interface. The Perl client is also still available.

For the application that automatically generates e-CRFs from CDISC ODM files with study definitions, we extended the application so that when a user uses one of the generated e-CRFs online, the submitted data are automatically converted into CDISC ODM format (ClinicalData section). This now means that it is possible to generate e-CRFs, use one of them and get submitted data back in ODM format in less than 60 seconds !

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.

## **Freely available for CDISC members: the ODM Checker v.0.5**

The CDISC ODM Checker is a tool for checking the integrity and consistency of CDISC ODM files. The checking goes far beyond checking against the XML schema or DTD, as it also checks on issues that are only described in the standards document itself. As such, the ODM Checker is an indispensable tool for all those working regularly with CDISC ODM files. As usual, it comes with a very user-friendly graphical interface.

The new version (v.0.5) now also checks ODM v.1.2 files, either using the new XML-Schema, or using the classic DTD. Inconsistencies in the ODM files are reported using messages that are very well understandable even by people that do have little XML-language knowledge.

Furthermore, the new version of the Checker has 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 download.

Licenses are also available for non-CDISC members on commercial basis.

More information about the CDISC ODM Checker, including a demo movie, is available at:

[www.XML4Pharma.com/CDISC\\_ODM\\_Checker/](http://www.XML4Pharma.com/CDISC_ODM_Checker/)

### **XML4Pharma teaching at the October DIA Meeting in Arlington (VA)**

As already mentioned in the previous issue of our newsletter, XML4Pharma has been invited to give an XML training at the DIA e-Clinical Interchange in October in Arlington (VA). We will be present on the first two days of the meeting (almost entirely devoted to the CDISC set of standards). So if you would like to have a meeting with us at the meeting, please let us know so that we can make an appointment.

**XML4Pharma is CDISC Registered Solutions Provider**



Registered CDISC Solution Provider



	<b>CDISC ODM &amp; Lab Implementation Workshop</b> How to make the promises of XML-based CDISC standards true
September 30, 2004 Munich, Germany	

**Information and Registrations at:**

**[www.cdisc.org/education/sep30\\_2004.html](http://www.cdisc.org/education/sep30_2004.html)**