

Bimonthly newsletter of XML4Pharma,  
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### **XForms: our services**

The standard is there. The first tools are there, the browsers and browser-plugins are there, and we have the necessary expert knowledge. Therefore we decided to start offering services in the area of XForms: development of XForms, automatic transformations from Schemas and other XML documents into sets of XForms (e.g. direct transformation from CDISC ODM Study definitions) and software development for working with XForms. So if you envisage to use XForms in your applications (Bristol-Meyers Squibb decided to), let us know and we will be able to provide you with the best services.

### **Soon available: upgrade of CDISC ODM Checker**

We are currently working on a minor upgrade of the CDISC ODM Checker. The new version will have improved checking for date- and timestamps, improved handling of <Include> elements, and will give support for checking ODM 1.2 files against the DTD.

A major upgrade, later this year, will also support checking ODM 1.2 files against their XML-Schema.

Keep an eye on our website for information about this new release. Please note that the CDISC ODM Checker is freely available for CDISC members (yet another reason to join).

### **In progress: the XML4Pharma application server**

XML4Pharma is well known for the evangelization and implementation of modern and innovative IT in Pharma R&D and Clinical. Our website contains a good number of pages dedicated to such new technologies. However, you might also like to see more of our technologies and applications in action or just try them out.

Therefore, we are currently setting up an application server that will allow you to try the technologies we evangelize. Examples are automatic generation and use of XForms, transformation of CDISC ODM documents into PDF reports, generation of e-CRFs, checking whether ODM documents conform to the standard (CDISC ODM Checker), trying out webservice (SOAP) etc..

Keep an eye on our website ([www.XML4Pharma.com](http://www.XML4Pharma.com)) to remain informed about the progress of this new project.

### **CDISC Protocol standard underway**

One of the missing links in the CDISC set of standards has been a standard to describe the set of protocols needed to start a clinical trial. A first proposal for a standardized framework and vocabulary has now been proposed by CDISC, HL7 and the FDA. When approved, the standard will be expressed as an XML-

Schema, allowing to describe protocols in a language that is both human and machine readable.

Full information about this new envisaged standard can be found at: <http://www.cdisc.org/standards/protocol.html>

### **First European CDISC Interchange meeting**

CDISC, the organization for standardization in clinical data interchange, will have its first European Interchange meeting from May 9-11 in Brussels. The meeting will take place in the beautiful area of the “Chateau du Lac” castle. Besides 2 days of lectures and presentations, there will be a number of pre- and post-conference courses. XML4Pharma has been asked to give

two courses. The first will be a basic XML course. We will explain how XML works using the CDISC ODM, how XSL stylesheets are used to transform XML documents, and also learn you to understand XML-Schema, using the new CDISC Lab standard as a working example. The second course is on implementation of the ODM and Lab standards in your IT environment. It will learn the participants how to extract information from a CDMS in ODM format (and vice-versa), how relational databases can be set up automatically from the Study section of the ODM, how to add and verify electronic signatures to CDISC files. Other topics include native XML databases, XForms (and how to generate them automatically) and Webservices to exchange data in a secure way over the internet.



**CDISC  
INTERCHANGE**  
Setting the Global Standard for Clinical Data

**CDISC EUROPEAN INTERCHANGE**  
Join us for a collaborative event to share progress, implementation experiences, and strategic ideas on worldwide data interchange standards for clinical trials.

**WORKSHOPS, TUTORIALS, CONFERENCE**

**9-11 May 2004  
Chateau Du Lac  
Brussels, Belgium**  
See <http://www.chateaudulac.com>

Additional information is forthcoming via email and the website @ <http://www.cdisc.org>

You're invited