Bimonthly newsletter of XML4Pharma,
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CDISC publishes ODM 1.3 for review

At the end of March, CDISC published the specification, XML-Schema and example files for the 1.3 update of the ODM standard.
The ODM 1.3 is fully downward compatible with the ODM 1.2 standard, but has many new exciting features and enhancements.

The specification, which is now open for comment, can be found at: http://www.cdisc.org/models/odm/v1.3/index.html

The 1.3 has a number of new datatypes (essentially, near all native XML-datatypes have been implementated), and considerable better internationalization and localization features. This means that using the ODM standard, an EDC or CDMS system can now be set up in/for any possible language.

The EDC capabilities have been considerably improved: logic for skipping questions, groups of questions, or even full forms or visits, can now be defined, as well in human-readable, as in machine-readable expressions (e.g. XPath expressions). More about this can also be found in our article on EDC, XForms and Ajax.

XML4Pharma at the Berlin CDISC 2006 Interchange

XML4Pharma had a booth at the CDISC Interchange in Berlin (April 26-27). Furthermore, Jozef Aerts gave a well-attended (25 participants) workshop on „Designing Clinical Studies Using the CDISC ODM and SDTM Standard“.

We also gave a lecture, together with Xavier Bessette of i-Clinics about how i-Clinics and XML4Pharma implemented the CDISC standards into the i-Clinics ClinCAPT data capture and data management system.

A photo of our booth can be found at the end of this newsletter.

The ODM Study Designer now launched

The ODM Study Designer is a new tool to set up clinical studies in ODM format. As the Study Designer first loads the ODM schema or ODM-extension schema, the tool can as well work with the ODM 1.2 as with the new ODM 1.3 standard.

Also vendor extension schemas can be loaded: the software itself takes care that dialogs and wizards for the vendor extension are automatically created. As such, the Study Designer is now already fully equiped to work with any future ODM extension (such as the recently announced WHO-protocol extension or even the future replacement for SAS Transport files).

The baptism of the ODM Study Designer took place at the European Interchange in Berlin: attendants to the workshop „Designing Clinical Studies Using the CDISC ODM and SDTM Standard“ used the software during the workshop, and received a free trial license for it. The software was also demonstrated at our booth.

The ODM Designer will be offered under a perpetual licensing scheme, with free updates until the end of 2007. For later updates, an upgrade licensing scheme will be put in place.

Full information about the ODM Study Designer can be found at our website.

A trial of the software is also available on simple request.

EDC, XForms and Ajax

We already had a demo application that allows the automatic transformation from CDISC ODM files in eCRFs (using XForms technology). With the new EDC capabilities of the new ODM 1.3 now available, we further extended the application, so that it supports the conditional appearance of questions and groups of questions (skip logic - see figure below). Also the internationalization features have now been fully implemented, allowing the automatic creation of eCRFs in any language for which forms descriptions have been made in the ODM file.

In general, eCRFs can be deployed in several ways. In most cases they require a thick client, i.e. a client on which special software has been installed. A new technology however, named **Ajax** (Asynchronous JavaScript and XML) now enables to use dynamic eCRFs (e.g. with skip logic) in any modern browser, as well on the PC as on a PDA.

DataLabs already has published about this technology and will probably implement it in its EDC systems (we asked them about this, but did not get an answer yet).

XML4Pharma is already watching the Ajax technology for a longer time. One of the remaining problems with Ajax is that the author of the eCRF still needs to write all the JavaScript and add it to the eCRF source HTML. In combination with the use of **XForms** however this doesn't need to be the case. We recently implemented Chiba-Web, an XForms implementation that uses Ajax technology. With the combination of our application that automatically generates eCRFs from ODM files and Chiba-Web, it is now possible to fully automate the creation of Ajax-enabled eCRFs without having to write a single line of JavaScript, or to edit the HTML page in which the eCRF is embedded.

The updated demo application (implementing ODM 1.3 and Chiba-web with Ajax) will become available on our public application server during the next few weeks at:

www.XML4PharmaServer.com

Does Oracle Clinical go CDISC ?

Oracle recently announced a new product (Oracle Clinical Data Respository) in their March press release. Special about this press release is that it mentions CDISC, even twice ! OC has not been known so far as an adopter of CDISC standards, but the times seem to change (we hope). The new product is announced to support "integrating clinical data from multiple sources" (sic) – which is what CDISC is all about, isn't it ?

Regulatory drive (say "the FDA") seems to be OC's reason for this policy change. From the press release: "The regulatory drive toward adoption of standards, such as CDISC, will compel life sciences organizations to standardize the way they manage their clinical data". Whether this means that OC will now become more or less ODM-compliant (import/export) remains the question. The press release gives us the impression that the new product concentrates on implementing CDISC submission standards first (such as SDTM and define.xml)

CDISC ODM Checker v.0.7 now available

Version 0.7 of the well-know and well-used CDISC ODM Checker is now available. This new version repairs some small bugs in the 0.6 version. As usual, the CDISC ODM Checker is freely available for CDISC member companies. A simple e-mail with your credentials suffices to obtain a copy of this software, which is used by many companies (including a number of CDMS and EDC vendors) for quality control of their ODM files.

Version 0.7 is not supporting the new ODM 1.3 standard yet (as it is still in the review period – so there might be some changes). As soon as the final version of the ODM 1.3 is released, we will start on adapting the ODM Checker for ODM 1.3.

The next release of the ODM Checker will very probably not support validation against a DTD anymore (why drive a Trabant if you can get a Ferrari for the same price ?). Only validation against XML-Schema will be supported. As of version 0.6, the CDISC ODM Checker already supports Vendor Extensions based on the ODM 1.2.1 Vendor Extension mechanism (also implemented in 1.3)

For the next version we also envisage a reengineering of the software. Since the very first version of the ODM Checker, new software technologies have become available for working with XML structures, and we can very well use these for coping with the new features of the ODM 1.3.

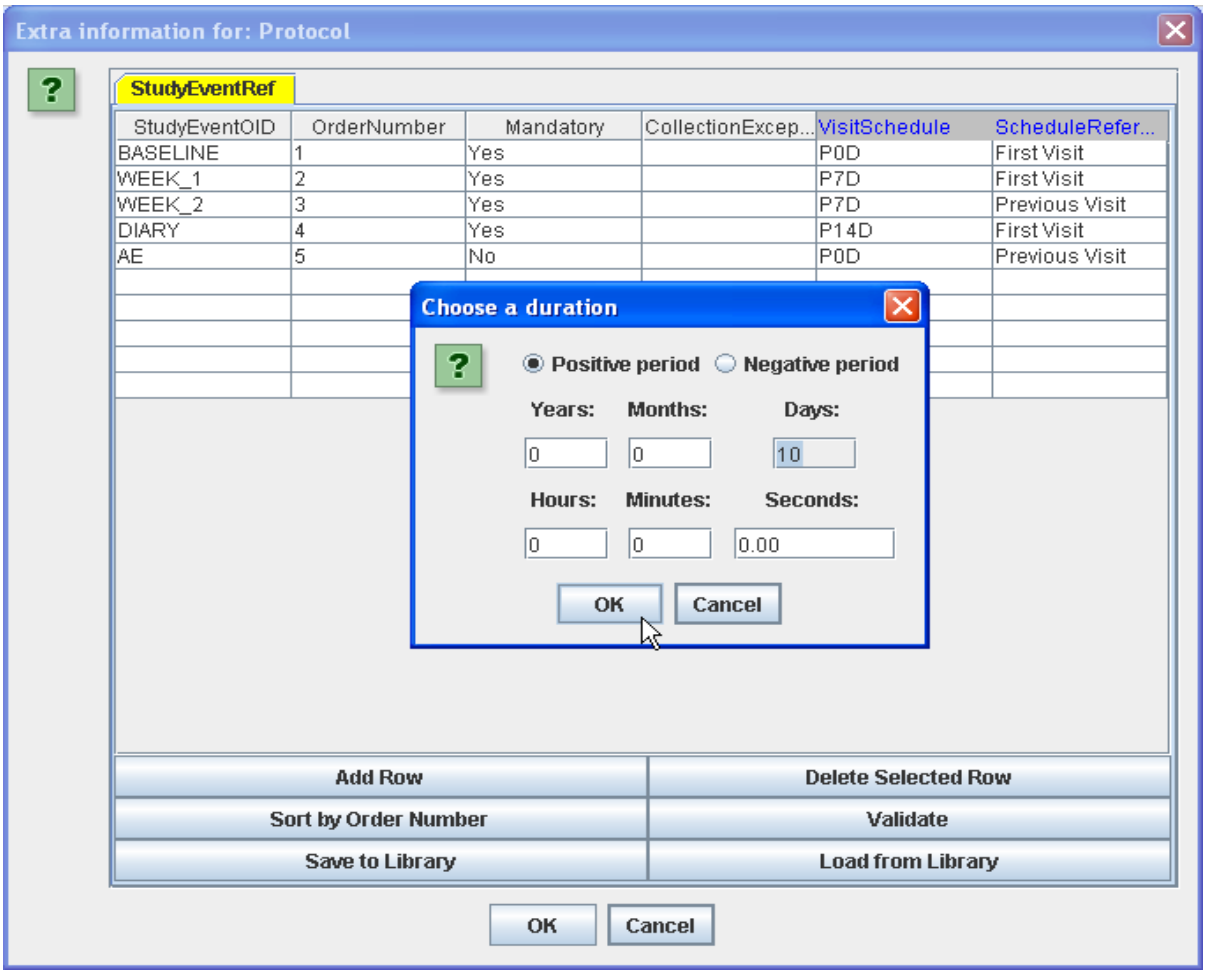
XForms 1.0 Second Edition is now a W3C Recommendation

On March 16th, the World Wide Web Consortium (W3C) announced that XForms 1.0 second edition is now an official recommendation.

The second edition was necessary to add clarifications to the specification, as some vendors had deviating interpretations about the standard. The second edition also has a number of new features, like an extra attribute on the "submission" element allowing to specify whether the XML send back from the server after submitting must be replaced in the form, or added to the form.

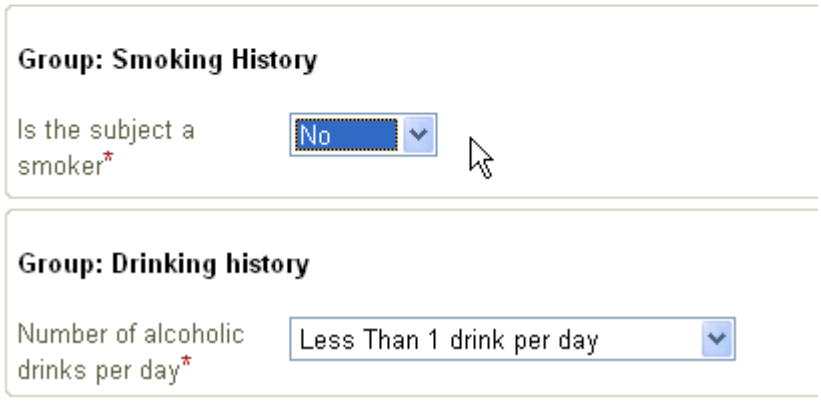
The specification of the second edition comes with an XForms Quick Reference, and a "Part 2 XForms for HTML Authors", which can be used as a tutorial.

XML4Pharma sharing a booth with Assero at the CDISC European Interchange



The ODM Study Designer

Dialogs and Wizards are automatically created from the XML-Schema.
In this case an ODM-extension schema is used allowing to define visit scheduling



One of the new great features of the ODM 1.3 standard:
defining conditions for not needing to collect certain data.
In this case, the question about the number of cigarettes disappears when the user clicks that the subject is a non-smoker
(eCRF automatically created directly from the ODM file,
using XForms, Chiba-web and Ajax technology)