Office closed for summer holidays

Our office will be closed from Monday July 30 to Friday August 17 due to summer holidays.
During this time I will however try to check incoming e-mail regularly, and answer the most urgent ones.

New features in SDTM-ETL^{TM} 1.1

We are currently developing version 1.1 of our SDTM-ETL^{TM} software for mapping CDISC ODM clinical data to CDISC SDTM submission data.

Version 1.0 is already the perfect tool for generating SDTM records for use in clinical data warehouses. Version 1.1 will also have the ability to generate the SDTM records in the classic SAS Transport format. This is a feature that has been asked for by some of our customers, as the XML format for submission data is currently still in development at CDISC. As soon as this format is published by CDISC, it will also be implemented in the SDTM-ETL^{TM} software.

Much more information is available at:
www.XML4Pharma.com/SDTM-ETL/index.html

The CDISC Intrachange

No, this is not a spelling error! CDISC recently organized an intrachange meeting for its volunteers in the working teams.

This intrachange took place from July 10 to 12 in Washington DC. The three day meeting was set up as a set of of working sessions, some of which were plenary, other team-specific, but also with many mixed-team sessions. The latter were sessions in which at least two teams exchanged information and ideas about how the different models can be integrated, in order to come to a single CDISC standard in future.

As an ODM team member (but also active in some other teams), I attended the meeting. It was all hard work, but it was worth it! Personally, I believe we made great progress. Even more important, I met all these great people (we were 90!) that make CDISC what it is. Even in the era of webconferences meeting people face-to-face is important, makes it easier to understand each other, so that rapid progress can be made.

An interview with Ilya Sterin from Nextrials

A short time ago, I found a very interesting article about the use of native XML databases and the use of CDISC standards in clinical trials.

The article was an interview with Ilya Sterin, who is a software architect and developer at Nextrials. Ilya is one of these people that were 'converted' to XML in an early stage, and one of the major contributers to the XML features of the Perl language.

Nextrials has based its EDC system on the CDISC ODM standard, and is using a native XML database from RainingData (see our previous newsletter). In the interview, Ilya comments on the use of XML as a transport format, and explains about the advantages of native XML databases.

Furthermore, his contribution to the open-source project XQOM (XML Query Object Mapping) is discussed.

Although the article is pretty technical, it is very well worth reading by all those interested in native XML databases and its use in clinical research.

The article can be found at:
http://www.theserverside.com/tt/articles/article.tss?l=IlyaInterview

CDISC publishes first ODM certifications

In our previous newsletter, we mentioned that XClinical and Clinphone are the two first companies that received ODM certification from CDISC for their EDC systems.

CDISC has now published the details of these two first certifications. They can be found at:

http://www.cdisc.org/odm/index.html

XForms 1.1 implementations

Many of our regular readers already know that we are evangelists of the XForms technology. XForms

is the successor of HTML forms, but much more powerful.

XForms 1.0 is a "W3C Recommendation" since early 2006, and XForms 1.1 currently has the status of "Working Draft". Version 1.1 of the standard is meant to remove some limitations of XForms 1.0.

XForms 1.1 has a number of new functions (including XPath2 functions), new datatypes (e.g. "email" - e-mail address), new actions (e.g. the "duplicate" action), and provisions for web services submissions (SOAP).

An important new feature is that the build-in datatypes (based on the base XML-Schema datatypes) now also allow empty content as being valid content. Before, when e.g. the item "Birthdate" in an XForm had been designated as being of type "date", then the field in the form automatically became mandatory, as the empty string is not a valid date. This wasn't of course meant to be so, as whether a field is mandatory or not is being regulated by the "required" attribute.

For those being involved in CDISC ODM and EDC, the XForms 1.1 datatypes are very close to those of the ODM 1.3 standard, making XForms the natural choice for implementing ODM 1.3 in electronic data capture.

Although XForms 1.1 has not received the status of "W3C Recommendation" yet, many companies and organizations have already started implementing the XForms 1.1 specification into their software and browsers. These include FormsPlayer, Mozilla Firefox, Mozzie, Chiba (limited), AjaxForms, and Orbeon.

Although almost all of our earlier developed XForms forms still work 100% correctly with the latest versions of these XForms implementations, we will soon start with upgrading our applications (e.g. the automatic generation of XForms forms from ODM 1.3 study definitions) to take advantage of the new features of XForms 1.1.

EDC vendors interested in applying the XForms technology are invited to contact us.

Restyling of the XML4Pharma website

Our website (www.XML4Pharma.com) has recently been restyled. This should make navigation and loading of the pages considerably faster.

The content and page locations themselves have nearly not been changed. So all information about our services, software offerings and information about modern XML technologies can still be found at the same locations as before (no need to update your bookmarks).