Bimonthly newsletter of XML4Pharma,
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Happy New Year !

First of all, we would like to wish all our readers a happy new year, good health and a lot of success in your careers and family life.

2006 may be a pivotal year. With economy becoming more healthy again, investments in modern technology are expected to rise, also in the pharma sector. So we expect a lot of activity in replacement of legacy software and processes.

As in 2004 and 2005, we will post our Newsletter every two months, and we hope to bring you exciting and interesting news.

XML4Pharma will keep evangelizing XML-based technologies, informing you about new tools and methods for working with the CDISC set of standards, but we are also planning to start looking into new directions, like other FDA-supported XML-based standards (especially HL7), We do also intend to expand our activities in the semantic web and RDF for Life Sciences (see the article further in this issue), which we believe is a further step in web based technologies for making drug development more cost efficient.

CDISC 2006 Interchange

The European CDISC Interchange will this year be held in Berlin from April 24 to 27. For those not having seen the announcements yet, they can be found at: www.cdisc.org/international/eu/eu.html

The first two days will be available for seminars and trainings, whereas the actual conference will take place on the 26th and the 27th.

As last year, XML4Pharma will have a booth at the exhibition, allowing us to inform all participants about our services, our CDISC tools, or just enjoy a German beer.

CDISC also extended the deadline for submitting abstracts for lectures until January 25. So if you have something interesting to tell at this conference, submit your abstract now !

eCliniqua predictions for 2006

Mark Uehling of eCliniqua requested the readers of his newsletter to make predictions about clinical technology developments in 2006. We pick a few interesting (abbreviated here) predictions from his latest newsletter (the full list can be found at the BIO-IT website):

- "Paper diaries will be virtually obsolete by the end of 2006"

- "You're going to hear a lot about EDC adoption"

- "EDC vendors are finding resistence to the cost. The typical CRO continues to build internal applications with Access and Excel"

The latter is about a complaint we hear a lot: "EDC (investment) is just too expensive". Personally, I believe that the cost of EDC can be reduced considerably by using standards (CDISC) and by using modern, inexpensive technologies (like automatic eCRF generation from CDISC ODM study designs).
In relation to this, it is interesting that we found a very recent article from Lorraine Ellis about the real costs and savings of EDC. It is the first article in which we found real life numbers about cost savings.

Achieving Cost Savings using EDC Effectively

This very recent article from Lorraine Ellis (Research Dynamics Consulting Group) gives an overview of advantages and disadvantages and cost factors of using

EDC. It is the first article in which I found a good amount of real life numbers about cost savings that can be obtained.
On the other hand, Lorraine's numbers show that there is a considerable shift in expenditure: when saving 28% in the example (470,000 $) trial, the internal costs are reduced to 219,000 $ (over 50% reduction), and the outsourcing costs (EDC vendor) increased to 119,000 $ (35% of the cost of the EDC trial).
So, with the new scenario, suddenly 35% of the cost of a trial needs to be used for paying the EDC vendor, a huge mental step for most of the CROs.

For clarity here a synopsis of Lorraine's numbers:

	Classic Trial	***EDC Trial***
Internal costs	**471,000 $**	**219,000 $**
External costs (EDC Vendor)	None	119,000 $
Total costs	471,000 $	338,000 $
Cost savings		28%

So, as already corresponded to my own opinion, the slow adoption of EDC by CROs is less caused by doubt about cost reductions, but much more by the huge organizational changes and cost shifts that are involved: assignment of new tasks and roles, re-education, staff reduction, unprecedented outsourcing costs, and requiring total trust in the capabilities of the EDC vendor, with the danger of a vendor-lock.

If the EDC costs themselves would be lower (through the use of standards and standard technologies), it would be considerably easier for the CRO to make a gradual change from paper to EDC.

Using standards and standard technologies, CROs would be able to gradually introduce EDC, buying low-cost components from different providers (construction kit principle), thus getting an EDC system that is tailored to their own needs, that is within their own control, and without the danger of a vendor lock.

The full article from Lorraine Ellis can be found at the ClickTrials website.

FDA updates XML-Schema for SPL

The FDA recently published an updated XML-Schema for validation of SPL (Structured Product Labeling) submissions.

The new XML-Schema allows to to describe packaging configurations where packages are provided within other packages.

Unfortunately, this update means that most vendors of SPL-software will need to update their tools too, unless of course their tool does already read the XML-Schema and automatically generates the widgets and wizards.

The new XML-Schema can be found at the SPL FDA website.

The new ODM Study Designer

In our latest issue, we announced the availability of the new CDISC ODM Study Designer, a new tool for designing clinical studies in CDISC ODM format. This new tool has drawn a lot of attention from pharma companies, as the tool allows them to design clinical studies directly in the CDISC ODM format. With a study designed in ODM format, otherwise cumbersome tasks, like setting up a CDMS or database, or the generation of eCRFs can be automated fully.

During the last weeks, we have further worked on full support for ODM Vendor Extensions: especially we developed intelligent widgets, wizards and dialogs for nearly all base XML-Schema types. This means e.g. that if a vendor extension states that an attribute VisitSchedule should be of type xs:duration, then a wizard pops up if the user wants to enter a value for VisitSchedule, so that it is impossible to

enter invalid values for that attribute (see picture at the end of this issue).

The ODM Study Designer is already made ready for the ODM 1.3 (this was easy, as the tool reads the XML-Schema and automatically generates all menus, widgets and wizards from the XML-Schema). So as soon as the ODM 1.3 will be published by CDISC, we will ship the tool together with the ODM 1.3, so that users can immediately benefit from all the new great features that the ODM 1.3 offers.

New on our website is also that you can download a (draft) copy of the ODM Study Designer User Manual.

CDISC Glossary version 4 available

CDISC recently published version 4 of the "CDISC Glossary" and "CDISC Glossary Abbreviations Acronyms" for review and comments. You can find them at the CDISC website.

The publication already triggered an interesting discussion (see the CDISC Discussion Forum website): Kerstin Forsberg from AstraZeneca proposed to have the Glossary being (also) published in RDF format. RDF (Resource Description Framework) is a framework to describe resources in a machine-readable (XML) form on the web. The RDF specifications provide a lightweight ontology system to represent semantics and to exchange interoperatable data on the Web. RDF is used for glossaries and taxonomies, and for linking data to the identified concepts. RDF is strongly related to the "Semantic Web", initiated by Tim Berners-Lee, the "inventor" of the world wide web.

XML4Pharma strongly supports this proposal to have more CDISC standards being published either as XML or as an XML-implementation (as RDF). Currently, the CDISC glossary is being published as PDF, which is essentially not machine-processable, e.g. a computer program cannot decide from the PDF document that "brand name", "trade name" and "propriety name" are synonyms. RDF allows exactly to describe this kind of relationships (and many others).

Related to this is of course the recent announcement of the founding of the W3C Life Sciences Semantic Web Group (HCLSIG). This group will be bringing together Semantic Web experts with life scientists (including clinical experts). One of the efforts will be to finding ways to make existing health care vocabularies and ontologies work within a Semantic Web context.

ODM on your PDA ?

With the venue of the ODM 1.3, automatic generation of eCRFs will become very easy. As a member of the ODM team, we are currently generating a multi-language ODM 1.3 Study Design example (using the ODM Study Designer), and developing the necessary technology to automatically generate eCRFs from ODM 1.3 files which can be used as well in a web browser as on a PDA.

The eCRFs themselves are in XForms (the new W3C standard for electronic forms).

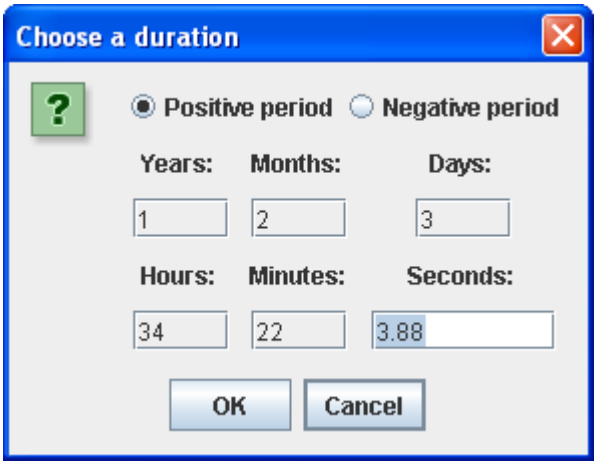
When the information from the form is send to the server, it is automatically transformed into ODM again, so that it can easily be assembled into a larger ODM file to be transferred to the sponsor.

Essentially, the use of these two standards (ODM and XForms) means that EDC becomes independent from propriety technology and avoids vendor lock: with these standards a CRO can e.g. choose EDC provider and CDMS independently, or even change EDC vendor in the middle of a study.

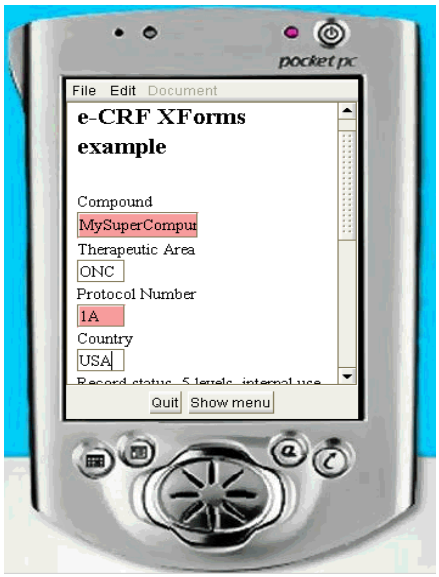
Currently we are testing the technology for deploying the eCRFs on PDAs (offered by several vendors).

XML4Pharma will demonstrate this exciting technology at the CDISC Interchange in Berlin in April.

One of the many wizards and dialogs of the new ODM Study Designer
The text (XML) format of this duration is: P1Y2M3DT34H22M3.88S



eCRFs on the PDA: now easily accomplished using CDISC ODM and XForms standards



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