Bimonthly newsletter of XML4Pharma,
Schlossbergstrasse 20, DE-78224 Singen, Germany
Phone: +49 7731 975044
Web : www.XML4Pharma.com
Mail: Info@XML4Pharma.com
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EDC threatened by dubious patent ?

Imagine a patent that claims the use of electric cars (known technology) for driving to the supermarket (known technology). Anyone using an electric car should pay a fee to the issuer of the patent. Ridiculous ? Not in the clinical world ! Bio-IT World recently informed us about a patent issued in 2001 by MLK Software (US Patent Nr. 6496827) that claims the "invention" of the use of the Internet for the capture of clinical data. The present patent holder (DataSci) already threatened Phase Forward and DataLabs with a lawsuit. A bit surprisingly, both companies quickly made a settlement with DataSci, with Phase Forward paying an amount of $8.5 Million (according to their press release). Another company under attack, eTrials, announced to defend itself against DataSci. Also Datatrak is seeming not to give in on DataSci, and is thinking of a counterclaim.

Will patent license costs for a dubious patent become a major component in EDC cost in future? Especially through the use of open standards (such as CDISC, XForms and others) the cost of EDC should go down in the future. But for the near future, patent issues may as well increase the cost of EDC considerably.

The changing world of clinical trials, DIA Basel, November 2006

Jozef Aerts of XML4Pharma will give a lecture at the next DIA meeting in Basel, with the title "From Protocol to Submission – the Value of CDISC standards. Experiences from a long-time Implementer". The lecture will give an overview of success strategies for and success stories of the implementation of CDISC standards in the clinical process. Also an overview will be given of current initiatives to better integrate the current CDISC standards. The presentation will take place on Wednesday November 8th. More details about the conference can be found at the DIA website.

ADaM 2.0 released by CDISC

CDISC has recently released version 2.0 of the "Analysis Data Model" (ADaM). The new version is now lining up with the SDTM standard. In the past, SDTM and AdaM were essentially two separate worlds, but much work has now been done to converge the two standards. Or literally: "The ADaM models and examples will build on Study Data Tabulation Model (SDTM) metadata models, adding attributes and examples specific to statistical analysis".
We believe this is a very good evolution, as it perfectly fits in the "Harmony" initiative of CDISC to harmonize all the CDISC models.

More information about the new ADaM standard can be found on the CDISC website.

Our latest article in Applied Clinical Trials

Our article "CDISC standards energize EDC" has just been published as feature article in the October number of "Applied Clinical Trials". The article treats the new features for EDC in the new ODM version 1.3 CDISC standard. Some of these new features include enhanced internationalization and the use of conditions for Visits, Forms, ItemGroups and Items. All together, the new version

now has all the necessary features to fully enable automatic EDC setup and automated generation of eCRFs in any written language.

The article is also available at: www.actmagazine.com.

CDISC Standards Energize EDC

Jozef Aerts of XML4Pharma details how the standard group's latest Operational Data Model version lets data managers leverage the full potential of electronic data capture in clinical trials.

Consolidation in Europe's drugs sector

The consolidation in Europe's drug sector continues. After the months long battle for Schering (finally won by Bayer, overbidding the German Merck), it is now the German Merck (not to be confused with the US company with the same name) that buys Serono, the Geneva-based biotechnology company. Only a few moments later, it was announced that Altana Pharma (with headquarters in Konstanz, not far from us) merges with the Danish company Nycomed.

Both Serono and Altana Pharma (but also Merck) are family-controlled pharma companies, and probably too small to be able to survive in a highly competitive, global market.

The combination of Merck and Serono would rank as one Europe's biggest pharma groups, with an annual sales of almost $10 billion, and a research budget of around $1.3 billion.
The combined Nycomed-Altana group is estimated to have an annual sales of over €3 billion (around $4 billion).

The CDISC ODM Checker as server application

Our CDISC_ODM_Checker is very popular amongst pharma companies, CROs and EDC vendors. This (for CDISC members) free tool is now already used by over 20 companies.

Many of these companies use the ODM Checker for quality control of incoming and/or outgoing ODM files.

What many people do not know, is that the ODM Checker can also be made available as a server application (the free version is a standalone application). A server application for example enables automatic quality control of each incoming ODM file. Other advantages are that the application can then centrally be maintained and deployed.

Also possible is to have the CDISC ODM Checker available as web service.

For more information about the ODM Checker as a server application, please contact us at info@XML4Pharma.com.

The ODM Study Designer version 1.1

In cooperation with our customers we are currently developing the requirements for the next version (v.1.1) of our ODM Study Designer. Some of the new features and enhancements that have already been decided on are:

- on-the-fly generation of test eCRFs
- enhanced visualization
- support for the upcoming CDISC Protocol (Trial Design) standard, as soon as the XML-Schema is published.

Full information about the ODM Study Designer is available at:

www.xml4pharma.com/CDISC_Products/ODMDesigner.html

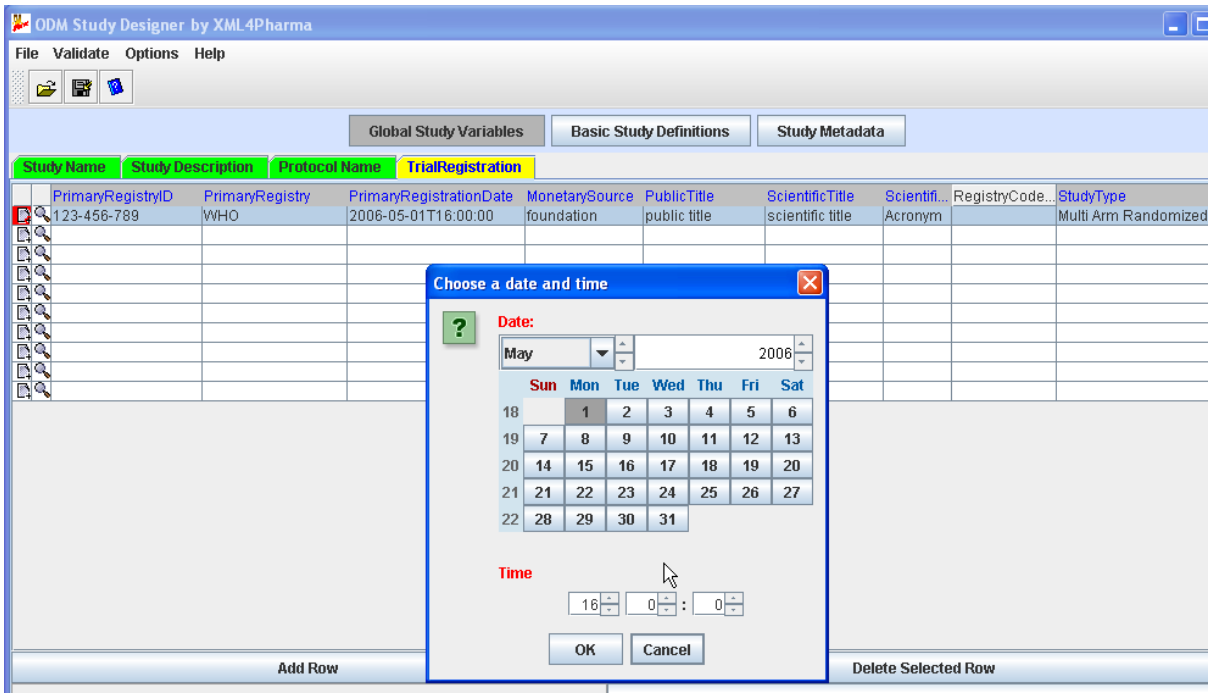
The ODM Study Designer and future CDISC Standards

CDISC has now clearly decided to use the ODM as a carrier of all its future standards. This means that for all new and existing CDISC standards, the ODM Extension mechanism will be used to define XML-Schemas for the technical implementation of the standard.

A WHO Clinical Trials Registry ODM-extension has already been developed and is currently in draft. Also other extensions, such as an extension for trial design (description of trial arms, epochs, visits etc..) are expected to become available in not too far future.

Using the ODM as a carrier for information created or collected for each of the CDISC standards also allows to come to a single, universal CDISC standard: all ODM extensions can easily be combined in a single super-extension, thus allowing to generate ODM files that e.g. contain as well trial design information, as collected clinical data.

As our ODM Designer is based on ODM Extensions schemas (all tables, menus and wizards are automatically created from the XML-Schema), the ODM Designer will support all these new CDISC standards, as it does already for Vendor Extensions of EDC vendors.



ODM Study Designer

The prototype CDISC standard for submitting trial registry information to the World Health Organization. The prototype WHO-extension schema is loaded in the ODM Designer (without any change), and all the input tables and wizards are automatically generated.