Bimonthly newsletter of XML4Pharma,
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CDISC to publish ODM 1.3

After a year of work by the ODM team, CDISC will now publish the ODM 1.3 specification before the end of the month. The ODM 1.3 is 100% downwards compatible, but has many new exiting features, especially for the use in EDC. For example, it allows to define conditions for the occurrence of (groups of) questions in an eCRF, or for the conditional use of forms and visits. The ODM is now fully internationalized, e.g. forms can be generated automatically in any language. New datatypes allow for improved data quality checking. Grouping of AuditRecords makes it easier for receiving systems to store ODM data in relational databases.

One of the examples that comes with the new version of the standard has been assembled by XML4Pharma (using the ODM Study Designer, see further). It demonstrates the extensive use of conditions for usage of forms, and conditional occurrence of (groups of) questions in forms. On our website, you can already see some of the automatically generated eCRFs at work.

In our belief, the ODM 1.3 is a great step forward for EDC vendors, as its use allows considerable cost reductions, especially for the development of eCRFs, which can now be fully automated.

As one of the co-developers of the ODM 1.3 standard, XML4Pharma will of course fully support this standard, and already now offers services for companies wanting to implement this newest version of the standard.

EMEA makes PIM Light Authoring Tool (LAT) available

EMEA has very recently made the PIM Light Authoring Tool (LAT) available for download. The website is:

http://pim.emea.eu.int/lat.htm

The LAT is software for setting up PIM (Product Information Management) submissions, which can be regarded as the European version of the FDA SPL (Structured Product Labeling).

The LAT tool has been implemented as a standalone Java WebStart application, based on technologies such as Struts and Java Servlets.

As EMEA itself will not provide training in the use of the LAT, we will start organizing trainings a.s.a.p.. With our knowledge of PIM (Jozef Aerts was the technical project leader when Organon did the first (in Europe) large electronic PIM submission back in 2001), and our excellent knowledge of the software and the technologies used in it, we believe to be a premier choice for delivering training services.

Furthermore, XML4Pharma will also deliver services to extend the LAT so that it interfaces with companies own processes and software systems. For example, we are currently investigating the possibility to deploy the LAT on a central intranet webserver (instead of as a standalone package), so that the LAT can be used in a multi-user environment.

European CDISC 2006 Interchange

The program of the 2006 European CDISC Interchange (Berlin, April 14-27) has now been published on the CDISC website. The Interchange consists of two days of trainings and seminars (of which one will be provided by XML4Pharma) followed by the two day confererence.

During the conference, we will give a presentation together with one of our customers (i-Clinics) titled „***Implementing CDISC LAB, ODM, and SDTM in a Clinical Data Capture and Management System: How We Did It***". Furthermore, XML4Pharma will be present with a booth at the commercial exhibition.

We hope to meet many of you at the CDISC Interchange !

XML4Pharma to give seminar at the CDISC Interchange

Also at the CDISC Interchange in Berlin, XML4Pharma will be giving a half day seminar (on Tuesday 25th) titled „***Designing Clinical Studies Using the CDISC ODM and SDTM***".

This seminar will learn the participants how to design and create a study in CDISC ODM format: setting up a protocol, study events, forms, itemgroups, items, codelists, internationalization, etc.., and how to add SDTM information to that study setup. The seminar will use the new CDISC ODM 1.3 standard. During the seminar, we will make a setup of a study from the bottom up. We will also add a small vendor extension (visit scheduling). As this is a hands-on seminar, participants should bring their notebook PC. We will use a new software program especially designed to construct ODM files. Participants will receive a demo copy of this software.For this seminar, only a basic understanding of the ODM is desirable. No knowledge of XML is required at all.

Registration information for this seminar can be found at the CDISC website.

The ODM Study Designer

The ODM Study Designer is a new tool (people at CDISC call this an „implementation enabler") to set up clinical studies in ODM format (v.1.2 or the new v.1.3). Unlike other tools, it allows to construct ODM files with study setup information without any knowledge of XML. Also, the tool is vendor-neutral. This firstly means that it allows you to use **any** vendor extension based on the ODM 1.2.1 (or 1.3) vendor extension mechanism. Furhermore it is not coupled to any CDMS or EDC system, nor does it use a propriety database (it does not use a database at all). Essentially, this means the ODM Study Designer makes you vendor-independent.

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

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

XML4Pharma starts Semantic Web activities

There is life beyond XML !

XML is a great technology, especially in combination with the internet. However, the web can offer much more than is now usually implemented. For example, if you have a reference to an external codelist in your SDTM system, how can your system validate the values in your submission against that codelist. You will need some programming, don't you ? How if that codelist was implemented as a web service by the organisation that maintains the codelist ? This would make life much easier isn't it ?

Currenly, we see some initiatives coming up (e.g. from NCI, the National Cancer Insitute) to web-enable codelists with their context (as CDISC is not the only organisation using codelists).

Another area where semantic web technologies can be very useful is in the CDISC Glossary. The latest version (v.4.0) has been published as a PDF file, but of course it would be better if applications

could look up the glossary and return information. Therefore, as an experiment, we are currently transforming the CDISC Glossary in SKOS (semantic web) XML format, so that it can later be used using a web service, or at least be available in electronic format.

CDISC Interchange 2006

Seminar: ***Designing Clinical Studies Using the CDISC ODM and SDTM***

Place and Date: Berlin, Tuesday, April 25th, 2006
Seminar Leader: Jozef Aerts, XML4Pharma

As this is a hands-on workshop, participants should bring their notebook computer.

During the workshop, the participants will:

- learn about the new features of the ODM 1.3 standard
- Develop of a vendor extension (visit scheduling) using the vendor extension mechanism
- Set up a simple clinical study in ODM format using a new software tool (trial version will be provided on CD)
- Learn how to add valuable SDTM information to the ODM Study setup.

No knowledge of XML at all is necessary, basic knowledge of the ODM standard is desirable.

For Registration Information, please visit the CDISC website at:
http://www.cdisc.org/international/eu/eu.html