

# XML4Pharma Newsletter

**Bimonthly newsletter of XML4Pharma, a subsidiary of  
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December 2002**



## XML4Pharma at InfoTechPharma

Jozef Aerts of XML4Pharma has been contracted to give the XML course at InfoTechPharma 2003, Europe's largest event for Information Technologists in the pharma and biotechnology industry. InfoTechPharma takes place from February 10-13<sup>th</sup> in London. Over 500 participants are expected, attending over 60 presentations, workshops, seminars and courses. The XML course concentrates on those XML technologies that are important for the pharma industry, with working examples such as eCTD, CDISC, ICSR. Also electronic signatures using and for XML documents are part of this course.

## XML4Pharma courses

If you are not able to attend InfoTechPharma, remind that we also offer this course (as a full day course) to pharma and pharma-related companies, on location, so that the participants do not have to travel. The course can then also be customized to the needs of your company. For more information about our courses and seminars, see our website.

## XML4Pharma and CDISC

Our involvement in CDISC (the Clinical Data Interchange Standards Consortium) is strongly growing. Besides volunteering as their European XML specialist, we now also have been asked to become member of the Conformity working group and the ODM working group. The latter is now starting with the development of a successor of the now already very successful Operational Data Model, the new (XML based) standard for exchange and archival of clinical data.

## The eCTD: publication of final release

The final specification of the eCTD (v.3) has now been released by the ICH (see [www.ICH.org](http://www.ICH.org)). This means that companies can start submitting their information to the regulatory authorities in this new, XML based format. A number of software companies have already started to sell eCTD-building software. These packages however do not allow lifecycle management of the eCTD, which might be company specific (different document management systems). When developing such an in-

house lifecycle management system, very good knowledge of XML and the eCTD is indispensable, which can be provided by XML4Pharma.

**All you need is SOAP**

SOAP is a relatively new methodology to allow software applications to “talk” (i.e. used methods of) other applications over loosely-coupled networks. SOAP is an important part of the so-called “web services” which are claimed to revolutionize the internet. Web methods however are also very important for intranets, especially there, where hardware and software is heterogeneous. The reason is that SOAP works using HTTP protocol, independent of hardware, operating system, or language in which the software was written. SOAP has the same goal as CORBA, but is much more flexible, and much easier to implement.

We are current SOAP-enabling a number of scientific (R&D) distributed applications of one of our customers, so that in near future, these application will be able to use each other methods. This will enable to automate these computing-intensive calculations, which now have to be started by hand, with a lot of cut-and-past and file manipulations. After SOAP-ing these processes, they will run with almost no human intervention, 24x7 hours instead of now 8x5, and with less (human) errors.

Interested in SOAP-ing your applications ? Just give us a call.

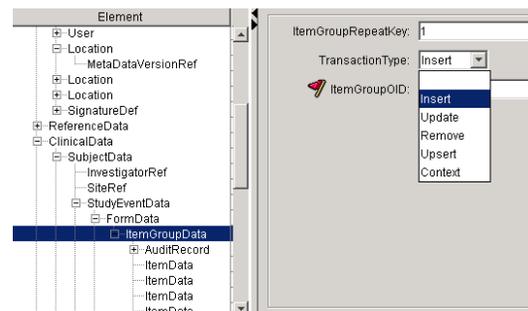
**ODM Editor and Reporter**

We are currently developing a prototype of an ODM editor and an ODM Reporter. The former will allow editing

of CDISC ODM documents, with special utilities like adding electronic signatures (using the new W3C standard), and retrieving and storing in XML-native databases or other XML-enabled databases. The same basis technology is also used in the prototype of an ODM Reporter, which loads ODM documents and transforms it (after filtering or not) into PDF format. For example, this software will allow to generate on-the-fly PDF reports for selected subjects (patients), users (doctors), locations (hospitals) and combinations of them.

The prototype will be developed to a commercial application if there is enough interest from the industry (sponsors and CRO’s). Also we would encourage the industry to provide input, so that we can develop an optimal product.

Name	SAS Dataset	Domain
Adverse Events	AE	AE Domain
Concom Meds	CONMED	Conmed Domain
Demography	DEMOG	Demog Domain
Treatment Assignment	DRUG_TRT	Treatment Domain
Pharmacokinetics	PHARMO1	PK Domain
Physical Exam	PHYEX	PE Domain
Sample Reference Data	REFSAMP	



**Snapshot of ODM Reporter and Editor**

### **Oracle announces XML DB and SQL/XML**

Until now, XML and SQL in databases were essentially different worlds. Although transforming SQL resultsets into XML documents is rather easy but requires some filtering and character transformation (for explanation and sample code see our website under “goodies”), there was no way to retrieve information using SQL from XML documents stored (typically) as LOB’s in sequential databases. For all these situations, a new standard, SQL/XML is being developed by a consortium of database companies (Oracle, Microsoft, Sybase ...). This new standard is expected to be ready by mid 2003. Just as an example, SQL/XML includes a new XML data type for use inside SQL.

Oracle’s XML DB is the first implementation of this emerging standard (available as of Oracle9i, release 2). XML DB allows storage of XML documents as a whole, or “shredded”, depending on the choice of the DBA (the application developer even doesn’t have to know), but also allows retrieving data from tables as well as from XML documents with one and the same query, where the result can either be output as hierarchical XML or as flat text.

More information about the SQL/XML standard can be found at [www.acm.org/sigmod/record/issues/0206/](http://www.acm.org/sigmod/record/issues/0206/) or at <http://otn.oracle.com/oramag/xmlquery.html>

### **Latest news: CDISC publishes production release of Lab standard**

CDISC (Clinical Data Interchange Standards Consortium) just released the specifications for the new Lab standard, for exchange of clinical laboratory results. The new specification was published at the CDISC website ([www.CDISC.org](http://www.CDISC.org)), and the XML implementation is expected to follow soon. Together with the ODM standard (we expect integration), this new open standard puts an end to the “jungle of standards”, leading to considerable cost decreases when exchanging clinical data between sponsors, CRO’s and clinical labs.

### **XML Signature**

The W3C released the XML Signature specification early this year, and already now some implementations have become available. XML Signature allows to sign everything that is electronically stored, from bitmaps to XML documents. The electronic signature itself is stored as an XML document, or in the case of signing XML documents or elements, it can be included within the document itself (enveloped signature). The implementation is a very secure one: as soon as one bit in the original document changes, the electronic signature becomes automatically invalid.

A demo (signing of CRF’s) is available on request.