CDISC Interchange 2005 - Paris

The second European CDISC Interchange in Paris was a very successful event with over 100 participants.
XML4Pharma was strongly involved in this yearly meeting: together with a colleague we gave the ODM course on Tuesday. We had a booth during the exhibition, and we gave a lecture on Thursday about tools for working with the ODM, Lab and define.xml standards

Especially our booth gave us the opportunity to present our services, our tools and to give a good number of demos, ranging from the ODMViewer to the use of automatically created e-CRFs in PDAs.

Next year's Interchange will in Berlin, around the same time as this year's.

News from EMEA: new version of PIM

EMEA has just published Version 1.2 of the PIM Data Exchange Standard (see http://pim.emea.eu.int/technical.htm). A number of important changes have been made. These have been very well documented, and also a new DTD (describing the XML structure for the submission files) has been published.

The website also contains all necessary documents, and two sets of example files. The latter also have a stylesheet associated with them to view PIM submission file in a very user-friendly and interactive way.

For me (Jozef Aerts) PIM has a special meaning. When I was still working for Organon, my regulatory colleague and I initiated the first large PIM submission in Europe. The pilot was very successful. After a programmer was send to an XML crash course, he was added to the team that successfully did the PIM submission in shorter time than expected, and without any major problems encountered during the project. It was the venue of the use of XML within Organon.

New brochure available on tools for working with CDISC ODM, Lab and Define.xml

We recently developed a 28-page brochure about tools for working with CDISC ODM, Lab and define.xml standards. The brochure can be downloaded from http://www.XML4Pharma.com/Tools_Brochure.pdf . Paper copies can of course also be obtained from us.

The FDA publishes about the use of the CDISC define.xml standard

A bit surprisingly, the FDA published information about the use of the define.xml standard on its website about three weeks ago. The document describes the specifications for the use of the define.xml standard for submitting datasets documentation to the agency. The new document can be found at: www.fda.gov/cder/regulatory/ersr/Studydata-v1.1.pdf .

Interactive e-CRFs and the CDISC ODM standard

The CDISC ODM allows to automatically generate e-CRFs from ODM files with Study metadata. Until now, what was lacking is the ability to generate "smart" or interactive e-CRFs directly from the ODM. An example of such a "smart' e-CRF is one where the question about pregnancy is blanked out once the investigator checks that the subject is male.

In e-diaries, there will be a lot of questions that become visible depending on

outcomes of other questions. So also there, dynamic and "smart" forms are used a lot. We already see that the ODM is also used a lot in electronic patient diarees, so to fully support "smart" dynamic forms, the ODM standard needs to be enhanced.

Therefore we made a proposal to the CDISC ODM team (of which we also are a member) to allow for the conditional use or appearance of StudyEvents, Forms, ItemGroups and Items. Technically this means that in the definitions in the metadata section of the ODM, the Mandatory attribute (which can now only get the values "Yes" and "No") receives an extra enumeration (e.g."Conditional"), and that an extra subelement (e.g. "Condition") is allowed to appear which is used for describing the condition (e.g. as an XPath expression, or instructions for the designer of the e-CRF).

The new ODM extension mechanism: new sample files available

We recently developed a new sample file demonstrating how the new CDISC ODM Vendor Extensions should be applied. Together with sample files provided by the SAS institute, and from the define.xml team, the set allows implementers to learn about this mechanism, with samples ranging from very simple extensions, to more complicated extensions, to a pretty complicated extension (define.xml).

One of the disadvantages of the schema files that were delivered with the first samples was that the computer system needed to be connected to the internet when the vendor extension is validated against the schema. Therefore we now also created a set of schema files (but with exactly the same functionality) for use in vendor extensions where the system is not supposed to be connected to the internet at all times. This makes it also possible to use

the vendor extensions in off-line devices, and still have the possibility to validate the input.

Both sets of sample files (one where internet connection is assumed, and one where it is not) are now available. Just drop us an e-mail and we will be glad to send them to you.

Archiving clinical data and ODM file sizes

We regulargy get the question: "when I archive my clinical data into ODM format, doesn't the file size become a problem ?".

Well, when archiving, one should not try to put everything in one file. A better practice is to archive in a chain of ODM files (e.g. one per subject). The FileOID and PriorFileOID attributes always allow you to rebuild everything in the correct order from the chain.

"But how can I then again inspect my data ?". One possible solution is to put a copy of all the archive ODM files in a native XML database. These databases are especially designed for very efficiently storing a large number of XML documents. Indexing can be applied to allow for even faster searching through the database. Native XML databases have one big disadvantage (but not for us): they need to be queried using XPath and XQuery expressions. XPath and XQuery are rather different from SQL, and there are not very many people yet that master these query languages.

Therefore we have put an XPath tutorial (tailored for querying ODM documents) on our application server, together with an example native XML database containing over 3000 small ODM documents. The application server can be found at: www.XML4PharmaServer.com.

XML4Pharma is a CDISC Registered Solutions Provider