SDTM-ETL™ 1.0 now available

Version 1.0 of the SDTM-ETL™ software for mapping and transforming CDISC ODM data into SDTM format, is now available for customers outside Germany[1].

The software allows to define even complicated mappings between ODM and SDTM in a very user-friendly way, to execute the designed mapping generating the SDTM data, and to create and populate an SDTM database.

The software was first demonstrated at the CDISC European Interchange in Montreux where it received a lot of attention.

We strongly believe that the SDTM-ETL™ software provides the "missing link" for the realization of the CDISC end-to-end idea, allowing the pharma industry to really use CDISC standards from protocol design up to submission to the regulatory authorities.

Much more information is available at:
www.XML4Pharma.com/SDTM-ETL/index.html

XML4Pharma at the CDISC European Interchange

The fourth European CDISC Interchange took place from April 23 to 26 in Montreux.

XML4Pharma was involved in the end-to-end workshop during the first two days, demonstrating the use of XForms for EDC and for integration of electronic health records (EHRs) with EDC systems. Also we presented our SDTM-ETL™ software as a solution for mapping clinical data in ODM format to the SDTM standard.

Furthermore, we had a booth at the commercial exhibition where we presented our services and our software offerings. Also there, we received a lot of requests to demonstrate the SDTM-ETL™ software.

During the conference, Johannes Hüsing (KKS Heidelberg) gave a presentation on "Automated mapping to simplify conversion of clinical data

from ODM to SDTM" using the SDTMWandler software, which was developed for TMF e.V. by XML4Pharma. More information about this presentation can be found on the TMF website.

Johannes Hüsing during his presentation on ODM to SDTM mapping

All together, the Interchange was a great success, with more participants than ever before (32% more than last year), and with a very large number of people attending one of the workshops.

All the presentations of the conference can be found on the CDISC website.

CDISC publishes Controlled Terminology

CDISC just published the final version of the SDTM Controlled Terminology Package 1 (including Laboratory test codes) and the proposal for package 2A (for public comment).

The publication of this controlled terminology is another great milestone in the integration of the

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1 The software is the further development of the SDTMWandler, developed for TMF e.V., who holds the marketing rights for Germany.

different CDISC models, in order to come to a single CDISC standard.

The codelists published by CDISC are meant to be used in SDTM submissions, but are of course also to be used as ODM codelists or in CDASH forms (which will probably also be published as ODM), and in CDISC Lab files (Lab Standard)

The great advantage of using these codelists right from the start, i.e. when designing the CRFs, is that no codelist mapping to SDTM needs to be performed at a later stage when the transformation of the clinical data data from ODM to SDTM data records is executed. Using the same codelists during data collection as for submission to the FDA saves a lot of work (and frustration) when preparing a submission using the SDTM standard.

The CDISC Controlled Terminology packages can be viewed at and downloaded from the CDISC website.

XClinical and ClinPhone receive ODM Certification from CDISC

At the European Interchange, it was made public that two companies have received ODM certification from CDISC.

XClinical (with Marvin) and ClinPhone (withClinPhone EDC) successfully passed the certification procedure for ODM compliance.

According to the press releases, ClinPhone EDC received the certification for its ODM export capabilities, whereas XClinical's Marvin EDC system received the certification for both import as export of ODM data, and the capability to automatically generate the eCRFs from ODM files with the study definition.

We are convinced that these two first certifications will boost the use of CDISC standards in electronic data capture, as it is clear that many other companies will now have to prove that their systems are really ODM compliant, instead of only claiming to "support CDISC standards".

As such, XML4Pharma is, and has already for a good number of years, been providing CDISC implementation services, helping EDC companies, CROs and sponsors with the implementation of CDISC standards.

XML4Pharma CDISC Implementation Services

One of our main activities is to help EDC and CDMS vendors with the implementation of CDISC standards, especially the ODM and Lab standards. As such, we already helped several EDC vendors

with CDISC implementation, either with consultancy, or even with full software design and software development for ODM/Lab import and export.

Now that the certification program is in place, we expect that these companies will soon apply for CDISC ODM certification. So do keep an eye on the CDISC website to see which companies receive ODM certification.

If you would like to obtain more information about our CDISC Implementation Services, just give us a phone call, or send us an e-mail.

New version of the ODM Viewer available

A new version of our popular CDISC ODM Viewer has just been released. Version 1.1 not only has full support for the new ODM 1.3 standard, but also has a lot of new features and improvements including:

- considerably better memory management, allowing to view and inspect much larger ODM files
- capability of viewing the ODM data as PDF, and to export these views as PDF files.
- "Scrolling memory" allowing to always return to a previous scrolling position (a feature that even commercial browsers do not have).

More information and a download of a trial version is available on our website.

New version of the ODM Study Designer available

Also our ODM Study Designer, a software package for the creation of clinical study designs in CDISC ODM format, has recently been updated. The new version (1.1) comes with new features such as:

- full support for ODM 1.3
- create, view and test prototype annotated eCRFs

The latter allows to generate prototype eCRFs on the fly without the need to upload the study design to an external EDC system. This allows a much faster eCRF design and development, while keeping working with the CDISC ODM format.

Information about the new version can be found on our website.

Nextrials bases EDC system on native XML database

Nextrials, an EDC vendor, recently announced a cooperation with RainingData, a manufacturer of native XML databases.

The Prism® PRT module allows to accept clinical data in any format and transform it into CDISC ODM format, which is then stored in RainingDatas TigerLogic® native XML database (also see our previous newsletter).

The advantage of using a native XML database is that the XML is stored as a whole in the database, and thus that a transformation to relational tables is not at all necessary. Many other EDC vendors do (still) use relational databases, which means that a mapping has to be designed between the ODM (or other XML) format and the relational tables. Also, upon import of ODM data, the latter first need to be transformed to be able to be stored in the database tables. As such, native XML databases can be much faster for storing and retrieving XML-based data.

The disadvantage of the use of native XML databases is that queries need to be done in the XQuery language. In this world, we have millions of people with SQL knowledge, but we do not have such an amount (yet) of people with XQuery language knowledge. XQuery is however not so difficult to learn, but it is quite different from SQL.

XML4Pharma is already advocating the use of native XML databases for a good number of years.

New software offering: the Define.xml Checker

How do you validate your define.xml file against the standard? Even more important, how do you check it for internal consistency? Are your referenced codelist correctly implemented, are all your referenced PDF files really present at their referenced locations?

A new software tool has just been released to check these and much more. We named it the "Define.xml Checker". It is based on our very popular "ODM Checker" but extended for all those extra rules as defined in the define.xml specification (formal name: CRT-DDS). As such, it makes it an indispensible tool for all those assembling define.xml files for use in electronic submissions to the FDA.

More information about the Define.xml Checker is available on our website.

Mozilla Foundation makes version 0.8 of XForms plugin for Firefox available

The Mozilla foundation has just made a new, improved version of the XForms plugin for Firefox, its very popular browser (35% market share), available for download. Although not all features of the XForms 1.0 specification have been implemented yet, the progress is such that Firefox with XForms plugin can now be extremely well used for production purposes, e.g. for collecting clinical data.

For those not aware yet, XML4Pharma has developed technology to automatically create eCRFs in XForms format from CDISC ODM study designs. This technology is currently being presented to EDC vendors.

Some life samples of eCRFs in XForms format can be tried out on our website.

The Firefox implementation of XForms currently seems to become a very popular one. This is probably due to the rapid progress that has been made in the last year, but also to the strong support it has received from IBM, who discontinued its own implementation.

XMLNotePad 2007

XMLNotePad is back! Years ago, when XML was still young, Microsoft published a simple XML viewer/editor names XMLNotePad.

Then, at some time, it disappeared from the web, just at the time where it became unclear whether Microsoft would support this new standard.

But XML survived, and also Microsoft started using it in its products.

As a consequence, Microsoft has given new life to XMLNotePad, and recently published the 2007 version. It is freely available from the Microsoft website.

Those thinking that XMLNotePad is a fully fledged XML editor are wrong. Although it provides XML-Schema validation, we were not able to validate an ODM 1.2 file against the ODM 1.2 XML-schema. We could however validate a CDISC Lab file in XML format against its XML-Schema.
Very probably, XMLNotePad does not well support schemas that reference other schemas, as is the case with the ODM 1.2 XML-Schema.

However, for simple XML work, the new XMLNotePad 2007 editor can be a pretty good XML editor, but its capabilities are not comparable to commercial XML editors such as Exchanger XML, oXygen, Xmetal, or StylusStudio.