

Bimonthly newsletter of XML4Pharma,  
Schlossbergstrasse 20, DE-78224 Singen, Germany  
Phone: +49 7731 975044  
Web : [www.XML4Pharma.com](http://www.XML4Pharma.com)  
Mail: [Info@XML4Pharma.com](mailto:Info@XML4Pharma.com)  
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## **SDTM-ETL™**

Transforming ODM data into SDTM datasets is usually not an easy process. Therefore, XML4Pharma has developed a visual, easy-to-use mapping software package for defining and executing ODM to SDTM mappings, and to create and fill an SDTM database.

This new software package goes beyond anything that is currently available to prepare SDTM datasets from clinical data. It is extremely user-friendly, and allows to define even complicated mappings without any knowledge of XML.

The introduction flyer can be found at the end of this newsletter. A brochure with more detailed information is already available at: [www.XML4Pharma.com/SDTM-ETL/Brochure.pdf](http://www.XML4Pharma.com/SDTM-ETL/Brochure.pdf)

The SDTM-ETL software will be launched officially at the CDISC European Interchange in Montreux in April.

## **CDISC European Interchange**

XML4Pharma will be participating at the CDISC European Interchange 2007 which takes place in Montreux (Switzerland) from April 23 to 26.

Join us at our booth for a discussion about our services or for a demonstration of one of our “CDISC Enabler” software tools!

We will also participate in the “End to End” workshop which takes place on Monday and Tuesday.

## **CDISC end-to-end**

As part of the CDISC European Interchange, XML4Pharma will have an active role in the CDISC end-to-end workshop. This workshop will learn the participants how the CDISC set of standards can be used starting from protocol design up to submission to the FDA. This one and a half day workshop will surely be one of the highlights of the Interchange.

Full information about the contents of this workshop can be found on the [CDISC website](#).

## **Upgrades of ODM Viewer and ODM Designer**

Our popular tools, the “CDISC ODM Viewer” and the “ODM Study Designer” are currently being upgraded (to version 1.1). Existing customers will obtain a free upgrade.

Some of the new features of the **ODM Viewer 1.1**:

- “softer” look-and-feel
- considerably better memory management: much larger files can be handled
- views can be saved as HTML or PDF files

Some of the new features of the **ODM Designer**:

- full support for ODM 1.3
- create, view and test prototype annotated eCRFs (see picture at the end of this newsletter)

The upgraded versions will be presented at the European CDISC Interchange in April in Montreux.

Also keep an eye on our website at: [www.XML4Pharma.com/CDISC\\_Products/](http://www.XML4Pharma.com/CDISC_Products/) for further announcements.

## **XQuery becomes a W3C Recommendation**

The World Wide Web Consortium (W3C) has recently announced that XQuery (XML-Query) has become a “W3C Recommendation”. The latter is the highest status a standard can obtain, i.e. it means that the standard is “final”.

XQuery is a language for querying XML data, whether it be on XML documents, on XML databases, or on any other data for which an XML view is available.

XQuery has its greatest use in native XML databases. Many of them (see also further in this newsletter) use XQuery for querying the database and construct new XML documents from the results of the query. These can then be visualized by a transformation into HTML or PDF.

As such, XQuery can be regarded as the XML counterpart of ANSI-SQL in the relational world.

## The future of the CDISC ODM Checker

Many of those working with the CDISC ODM standard know the product pretty well: the [CDISC ODM Checker](#). It is a free tool (at least for CDISC members) to validate CDISC ODM documents (version 1.1 or 1.2) against the standard and for internal consistency.

The first version of the ODM Checker was developed some five years ago, at the time that there was little technology available for working with XML documents. For example, at that time working with DOM (Document Object Model, i.e. loading XML documents in memory) was a nightmare, XPath was still in its early development, and almost no libraries were available for working with XML documents.

Nowadays however, much more is possible, and many of the earlier used external libraries are now core in modern programming languages like Java and C#.

Meanwhile, CDISC also published the ODM 1.3 standard, which has considerably more features than the previous 1.2 standard (see our [previous newsletter](#)). As more features also means more rules, this means that the ODM Checker needs an upgrade.

We decided that this was a good moment for a reengineering of the ODM Checker, allowing to implement the latest available technologies. The amount of work involved was estimated to be about 3 man-months. As we do however want to keep the ODM Checker free-of-charge for the CDISC community, we came to an agreement with the [University of Heidelberg](#), [Institut für Medizinische Biometrie und Informatik](#), to have the new version reengineered and developed by a student as a “Diplomarbeit”.

This process has now been started. For their contribution to the CDISC community, we already want to thank all the people involved at the Heidelberg university for their enthusiasm and commitment!

We expect that the new ODM Checker will become available in autumn.

## New CDM System based on CDISC ODM and native XML database

RainingData®, a vendor of native XML databases, has recently announced a new clinical data management system based on the CDISC ODM standard and their TigerLogic® XML database.

In their system, any incoming clinical record is transformed into CDISC ODM (if not already in that format) and stored as ODM XML in the XML database. Quality rules can be defined by the sponsor: if an incoming clinical record does not pass the quality checking, it is send back to the CRO, together with a “Data Clarification Form”. “Data Quality Reports” can also be created from the database contents, allowing the sponsor to check the quality of the incoming data e.g. per CRO as function of time.

Queries can be applied on all documents in the database using queries in the W3C XQuery Standard language.

More information about this new clinical data management system can be found on the [RainingData® website](#).

## XML4Pharma and EDC Vendors

It is a question regularly asked by individuals and companies that contact us: “*What is your relation to EDC and CDMS vendors – is XML4Pharma an EDC vendor itself?*”.

No, XML4Pharma is not an EDC vendor. We are a technology company that develops new technologies mostly based on the XML standard and its related standards (XSLT, XPath, XQuery ...) and applying these to the pharma world. Furthermore, as a “CDISC Registered Solution Provider”, we evangelize, help to develop, and implement the CDISC set of standards.

As such, EDC and CDMS vendors are a vast part of our customer base. **If your EDC or CDM system can “read and write” CDISC, it may well be that XML4Pharma has done the implementation!** XML4Pharma has already helped a good amount of EDC and CDMS vendors worldwide with CDISC implementations. In many cases this also included writing or adapting the necessary software and/or the database system.

Furthermore, XML4Pharma has pioneered and is still pioneering in many areas of XML applied to the pharma world. Examples are the use of web services for exchange of clinical data, use of XSLT for visualisation of XML documents (e.g. to HTML, PDF, ...), the use of native XML or mixed relational-XML databases, and the use of the XForms standard in EDC (eCRFs) in combination with the CDISC ODM standard.

As an early implementor, we then are often first choice when EDC/CDMS vendors want to implement these technologies.

Annotated eCRF preview - form: F\_BASELINE - Ligne de base

<b>General</b>	
Numéro de la clinique	23
ID du Sujet	SUB001
Date de Visite	2007-03-02 <input type="button" value="Calendar ..."/>
<b>Demographie</b>	
Date de Naissance	<input type="button" value="Calendar ..."/>
Genre	SDTM Variable Name: BRTHDTC Masculin
Appartenance ethnique	Masculin ERROR: NO TRANSLATION GIVEN YET
<b>Histoire consommation du tabac</b>	
Est ce que le sujet est fumeur	Non
Nombre de cigarettes par jour	Moins que 10 cigarettes par jour
<b>Histoire consommation de l'alcool</b>	
Nombre de boissons alcoolique par jour	Moins que une boisson par jour
<b>Examination du corps: Base</b>	
Taille	

<b>Adverse events</b>	
Event No.	SDTM Domain: AE
Adverse event	
Start Date	

<b>Adverse events</b>	
Has the subject experienced any adverse events	No
<b>Adverse events</b>	
Event No.	
Adverse event	

Data type : codelist - integer

One of the new features of the [ODM Study Designer v.1.1](#): create and test prototype annotated eCRFs ... in any language.



4th European Interchange

23rd—27th April 2007

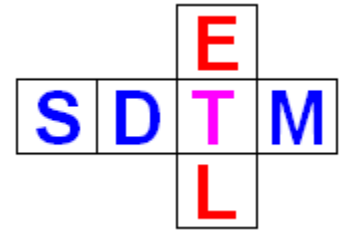
Grand Hotel Suisse Majestic

Montreux, Switzerland

Join us at the 4<sup>th</sup> CDISC European Interchange !



# SDTM-ETL™



## A user-friendly ODM – SDTM Mapping software package

Transforming CDISC ODM datasets with clinical data into SDTM datasets is not an easy process.

Therefore, XML4Pharma has developed a visual, easy-to-use mapping software package for defining and executing ODM to SDTM mappings, and to create and fill an SDTM database.

The SDTM-ETL™ software package is a real ETL software tool allowing to:

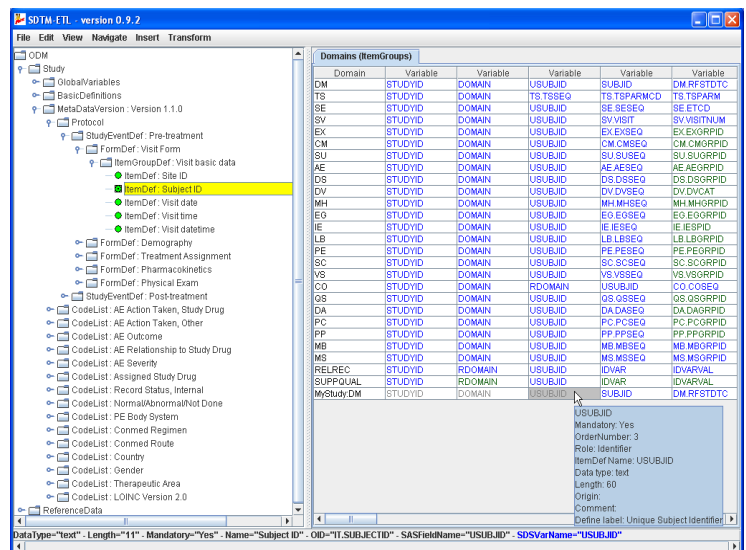
**Extract:** ODM metadata and clinical data from ODM files

**Transform:** describe (even complicated) mappings between ODM and SDTM and execute them

**Load:** create an SDTM database and load the SDTM data into the database.

### Mapping features:

- create mappings using drag-and-drop
- combine ODM data into a single SDTM variable
- perform calculations on ODM data to create an SDTM variable
- many mathematical and date/time functions provided
- “CDISC Notes” on each SDTM variable for background information
- Easy-to-learn scripting language
- Many wizards provided for auto-generation of scripting snippets
- “Test” button to test mapping scripts on clinical data



### Transformation features:

- mapping scripts are transformed into XSLT which is executed on the ODM clinical data, resulting in SDTM datasets in XML format (precursor of CDISC SDTM-XML)
- automated generation of SUPPQUAL domains when necessary
- Offline transformation is possible
- Generation of define.xml file (for submission to the FDA) from the study-specific domains and variables

### Database features:

- create SQL statements for generating a relational SDTM database from the study-specific domains and variables
- Transform and load the generated SDTM records into the SDTM database