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**XML4Pharma is a CDISC
Registered Solutions Provider**



ODMDesigner 2010-R2

We have just released v.2010-R2 of our well-established “[CDISC ODM Study Designer](#)” software.

The software now has not only full support for the new ODM 1.3.1, but also many new features, especially for inspecting the study design in different ways. For example, a “deep tree” view with HTML tables has now been added (see image at the end of this newsletter).

A copy of the “New features” document can be downloaded [here](#).

Also the performance and the memory footprint have further been improved decreased, meaning that also very large libraries (such as the public “Lilly ODM library”) can be loaded.

For academic research and teaching, the new version is available with an 80% discount.

More information about the new release is available [on our website](#).

SEND v.3.0 for public review

In our last newsletter we discussed the by CDISC published draft version of the “Metadata Submission Guidelines”. We did not like it so much.

We now also reviewed the “SEND 3.0a” draft Implementation Guide. In contrast to the former document, the draft SEND-IG is a jewel.

I must say honestly that I have not seen any publication from CDISC so far yet that is so clear, so full with examples and explanations as this document. So my very sincere congratulations to the SEND team for this magnificent work.

Of course there are some errors in the draft, or things that could be done better, so we did send in our comments. Overall however, I found this document to be of very high quality.

But have a look for yourself, and [download the draft SEND-3.0 IG](#) from the CDISC website.



Standard for Exchange of Nonclinical Data Implementation Guide: Nonclinical Studies

Prepared by the
**CDISC Standard for Exchange of
Nonclinical Data Team**

We are also currently working on implementation of this new standard in our [SDTM-ETL™ software](#). As soon as the SEND v.3.0 becomes final, we will release a new version of the SDTM-ETL™ software that implements SEND v.3.0.

German User Group Meeting – Berlin 28.9

The German-speaking CDISC User Group has its semi-annual meeting at Parexel in Berlin on September 28.

The theme of the day will be CDASH. The day will be organized as a workshop, with many speakers sharing their experiences how CDASH was implemented in their company. Also the ODM implementation, and the (still draft) version 1.1 of the CDASH standard will be discussed.

Full information about the event is available on the [CDISC portal](#).

ODM wiki

Many people still seem not to have found the ODM Wiki yet that we maintain. It has been published at: <http://www.xml4pharmaserver.com/XML4PharmaWiki/doku.php>.

It contains a lot of information about how the ODM can (and should be) used, with many examples, and also a number of articles about “good” and about “bad” practices.

This Wiki is surely the first address to visit when questions about the ODM standard and its implementation occur.

The Wiki is regularly updated and extended. So be sure to visit it regularly!

XML4Pharma at the DIA 2011 Geneva Eurometing

Our abstract has been accepted, so we have been invited by the DIA to give a presentation at the 2011 Geneva Eurometing (March 28-30).

The presentation will be titled “Almost there! CDISC end-to-end using one standard set and one format”. It will explain the relationship between ODM, CDASH, SDTM, SEND and ADaM, and especially how a single format can be used to transport any of the above data to its next stage in the clinical data workflow (end-to-end).

The early/preliminary program of the DIA Eurometing can be found [here](#).

The screenshot displays the ODM Study Designer interface. On the left, a tree view shows the study structure, including 'Study', 'GlobalVariables', 'BasicDefinitions', 'MetaDataVersion: Study Version 1', 'Protocol', and 'StudyEvent: Initiation'. Under 'StudyEvent: Initiation', 'Form: Visit Information' is expanded to show 'Form: Demography', which contains an 'ItemGroup: Demography'. This group includes items like 'Date of Birth', 'Subject age at visit date', 'Sex', and 'Race', along with various 'CodeList' and 'Method' entries.

The main window shows a search bar and a table of item groups. The table has columns for Name, OID, Repeating?, Reference Data?, SAS Dataset Name, Domain, Origin, Role, and P. The 'Demography' item group is listed with OID 'IG.DEMOG' and 'Repeating?' set to 'No'. Below the table, there is a section for 'Item Group Description' with a table for 'Language' and 'Translated Text', showing 'en' for 'Demography'. A search dialog box is open, titled 'Find tree node by OID/Name', with 'Find by Name' selected and 'demography' entered in the 'Name to find' field.

“Deep Tree” View in the new release of the ODM Study Designer
The hyperlinks in the HTML panel on the right open up a new window with additional information about the specific item or component

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