Bimonthly newsletter of XML4Pharma,
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November 2005

A new tool for designing clinical studies in CDISC ODM format: the ODM Study Designer

Setting up clinical studies in CDISC ODM format has many advantages. It allows to exchange the study setup information in a standardised, vendor-neutral format. Moreover, as CDISC ODM is based on XML, it allows automation of otherwise cumbersome and time consuming tasks like database creation, setting up the CDMS, design and generation of e-CRFs, etc..

Until now, a good, affordable software tool for setting up clinical studies in ODM format was not available. Some people used an XML Editor like XMLSpy to generate the Study setup in ODM format, others did not use the ODM at all and kept sending Study and Protocol information as Word documents or PDFs to the CRO, EDC company or other partner in the clinical process.

Therefore we developed the ODM Study Designer, which allows to set up clinical studies in ODM format without any knowledge of XML at all. The tool is very user-friendly, as it works with many dialogs and wizards, so that also users who are new to CDISC ODM can learn very quickly how to generate Study information in ODM format.

The tool has been developed so that Vendor Extensions based on ODM 1.2.1 are fully supported: the ODMDesigner reads the XML-Schema with the vendor extensions and base ODM XML-Schema and automatically creates all necessary tables and dialogs.Of course, also the upcoming ODM 1.3 standard is fully supported.

The tool is SDTM-ready, which means that the user can add domain names and variable names from lists taken from the SDTM 1.1 (SDS 3.1) specification.

As the tool reads and writes ODM (no propriety formats are used), it eliminates software vendor-lock for designing clinical studies and eCRFs.

We expect that this tool will further boost the use of the ODM standard in setting up clinical studies: with this tool, there is no excuse anymore not to use the ODM standard right from the start of the clinical study process.

The reader can find some screenshots at the end of this newsletter.

Further information about the ODM Study Designer can be found on our website at:

www.xml4pharma.com/CDISC_Products/

Four Worlds – One Vision: DIA Conference Prague

The latest DIA conference in Prague was a very interesting one, as the “hot topic” of the conference was the use of EDC and its impact on Clinical Data Management and Regulatory.
Although there was a special e-Clinical stream, the EDC topic came back in almost every lecture of the other streams. Furthermore, a large number of EDC Vendors was present at the commercial exhibition.

Personally, I found a number of lectures about “mixed” trials, i.e. trials in which as well EDC as paper was used, very interesting.

There was a lot of discussion about the cost and ROI of EDC. Especially CROs keep having the feeling that EDC is not affordable. What was underexposed in my view, is that the use of (CDISC) standards

in EDC can enormously reduce the costs. So maybe I should give a lecture on that topic at one of the next DIA conferences.

CDISC Lab Standard implementation

We heard it again at the last DIA meeting in Prague: CROs still believe that the use of the CDISC Lab standard is not affordable for small laboratories with which they cooperate. That is nonsense of course! Instead these CROs invest large amounts of money in systems that allow them to transform data from small laboratories into their own formats. This is an expensive exercise, as each of these small laboratories usually has its own, propriety formats, or have to maintain a large number of different formats of their customers.

A number of projects XML4Pharma executed sofar for CROs and small and mid-sized clinical labs clearly prove that the CDISC Lab standard can be implemented at an affordable cost, and that this investment quickly pays back.

An excellent article on the use of the CDISC Lab standard and its benefits was recently published in Applied Clinical Trials. The article states that the cost reduction of using the CDISC Lab standard is between 30 and 50%. This is considerable, as it has been estimated that 60-80% of clinical data originates in laboratories. Some centralized labs have even offered preferential pricing for customers that agree to receive the test data in CDISC Lab format.This, as the use of the standard saves them a large amount of time and money.

XML4Pharma is one of the pioneers in the development of tools for working with CDISC Lab files. A number of our tools can be tried online on our free application server. This includes a tool for checking CDISC Lab files in ASCII or in XML format against the standard, and a conversion tool that transforma CDISC Lab files in ASCII format to CDISC Lab files in XML format.
Other tools for generating Lab files or to work with CDISC Lab files have been developed for some of our customers on project basis.

CDISC ODM 1.3: new features and enhancements

We are almost so far: the ODM team expects to be able to publish version 1.3 of the ODM standard for comment on the CDISC website before the end of the year.

Although 100% downwards compatible, version 1.3 has a good amount of new exciting features, especially for use in EDC and clinical data management. EDC vendors will especially appreciate further internationalization in Forms and the ability to use conditions for the use and occurrence of items, itemgroups, forms and even study events. For data transfer and archiving, the most interesting new features are the new data types, these e.g. allow to have binary data in an ODM file. Furthermore, the problem of partial and incomplete dates and times have now been solved using these new data types.

Automatic generation of e-CRFs from ODM study setups : technology now generally available.

A number of EDC vendors already do it: generating eCRFs directly from CDISC ODM files containing study setup information. With the new version 1.3 of the ODM standard, this will even become considerably easier (see previous topic). Most EDC vendors use propriety technology for performing the transformation from ODM to e-CRF, driving sponsors and CROs into an expensive vendor lock.

There is however good news: XML4Pharma has developed a technology, based on XForms, the open W3C standard for web-based and standalone forms, which enables to generate eCRFs on the fly at low cost. This XForms technology has now become so mature, and more and more XForms enabled browsers and PDA XForms software becomes available, that we decided to start offering this technology to sponsors, CROs and EDC vendors, based on a “technology transfer agreement”.

The use of W3C standardised XForms technology must so further enable to make EDC much more affordable, and eliminate vendor lock.

The technology can already be tried out at our demo application server: the user can submit a CDISC ODM file with Study information (samples are provided), and then gets a set of eCRFs back, which can be populated online and submitted. The end result is than presented in the form of a CDISC ODM ClinicalData file and a PDF file with the form data.

CDISC ODM Checker v.0.6 now available

In the last issue of our newsletter we announced v.0.6 of our CDISC ODM Checker, a conformity checking tool for CDISC ODM files. This new version has now become available.

The new version has a number of improvements against v.0.5, including support for vendor extensions based on ODM 1.2.1, the ability to save or print the results of a conformity check, and many small improvements for conformity checking of ODM 1.2 files with XML-schema.

The CDISC ODM Checker is freely available for CDISC member companies. Non-members can acquire a license.

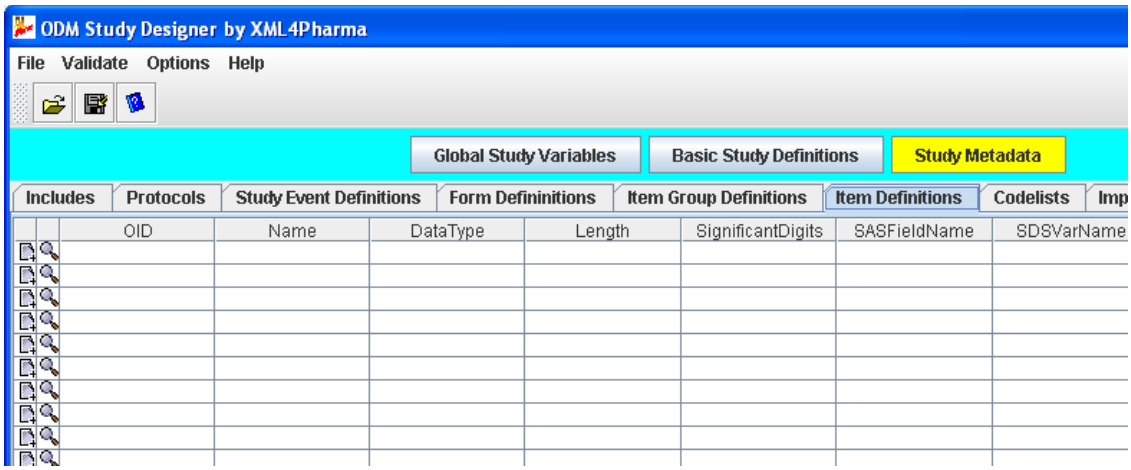
Most recent new users of the CDISC ODM Checker are PRA International and Octagon Research.

IBM Releases XForms Generator

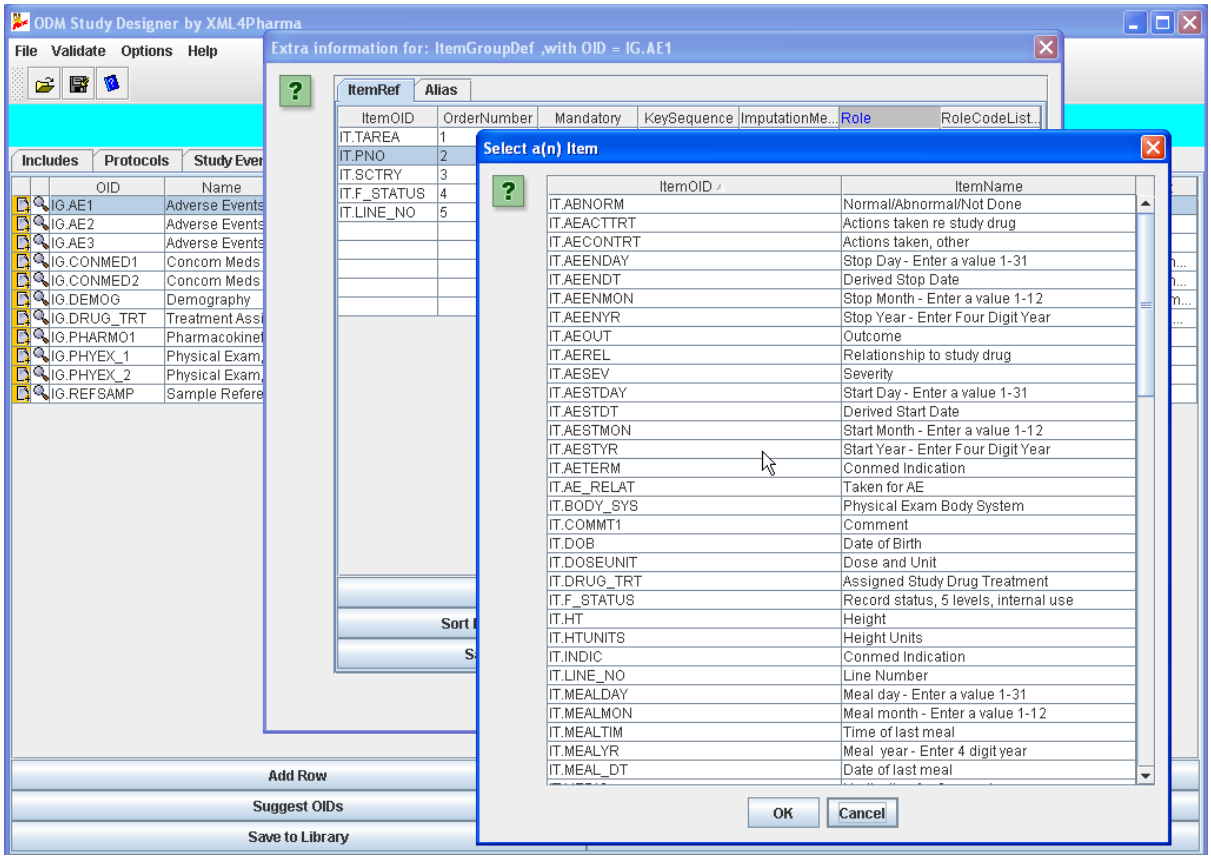
IBM recently released an update of its XForms Eclipse plugin. Using this software (which runs in the extremely popular Eclise Java IDE), it is possible to generate XForms from instance XML documents and their respective XML-schema. The generated XForms can then be rendered into a number of popular XForms browsers and renderers, including FormsPlayer, Chiba, X-Smiles, Novell, Mozilla Firefox and others.

Although the tool is not suitable to directly generate e-CRFs in XForms format from CDISC ODM files, it can be very helpful in making improvements (e.g. in the layout) of automatically generated eCRFs with our technology, and to test them in different browsers and XForms renderers.

The ODM Study Designer: screenshots

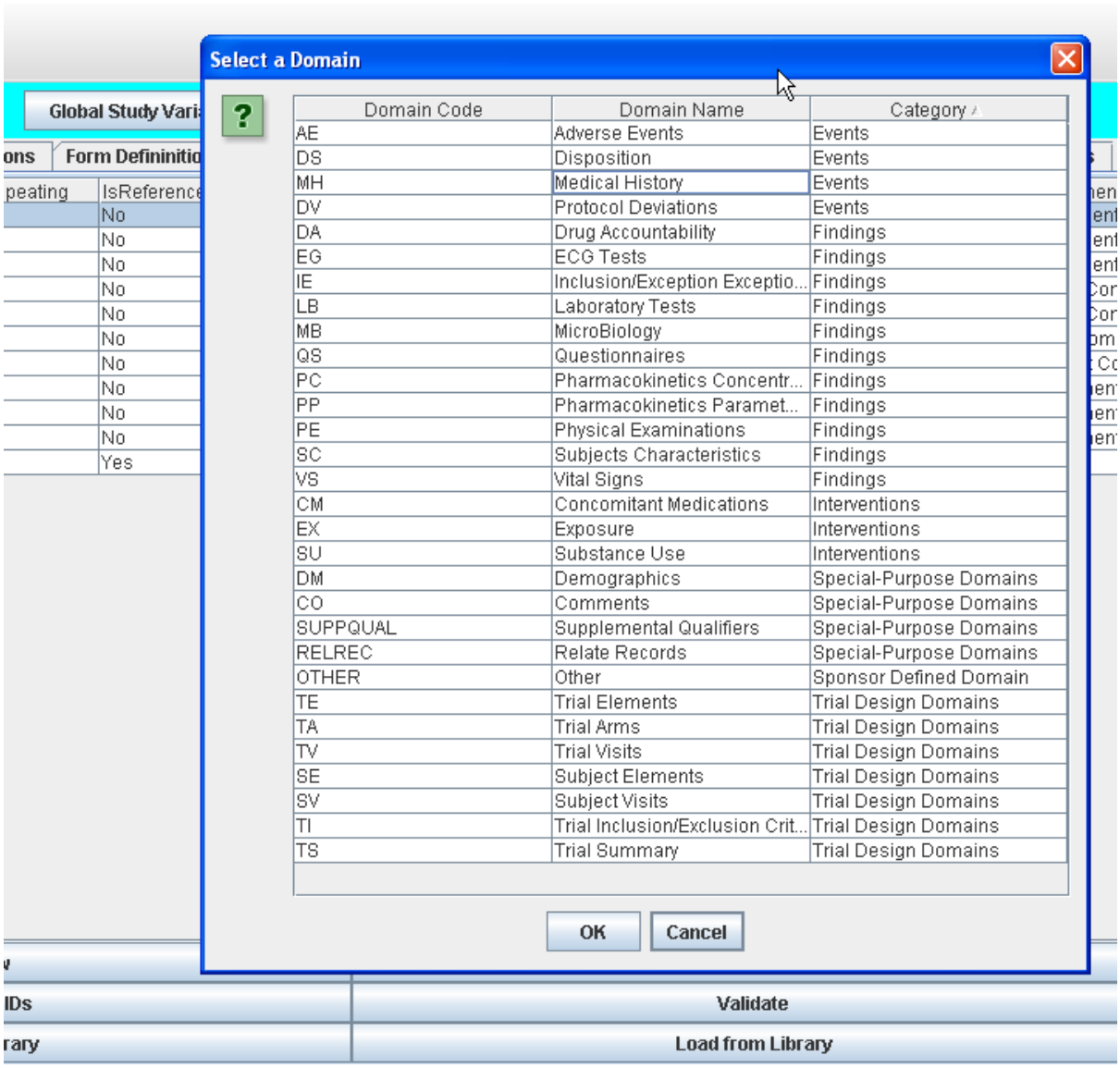


The table templates, dialogs and wizards are generated from the ODM XML-schema



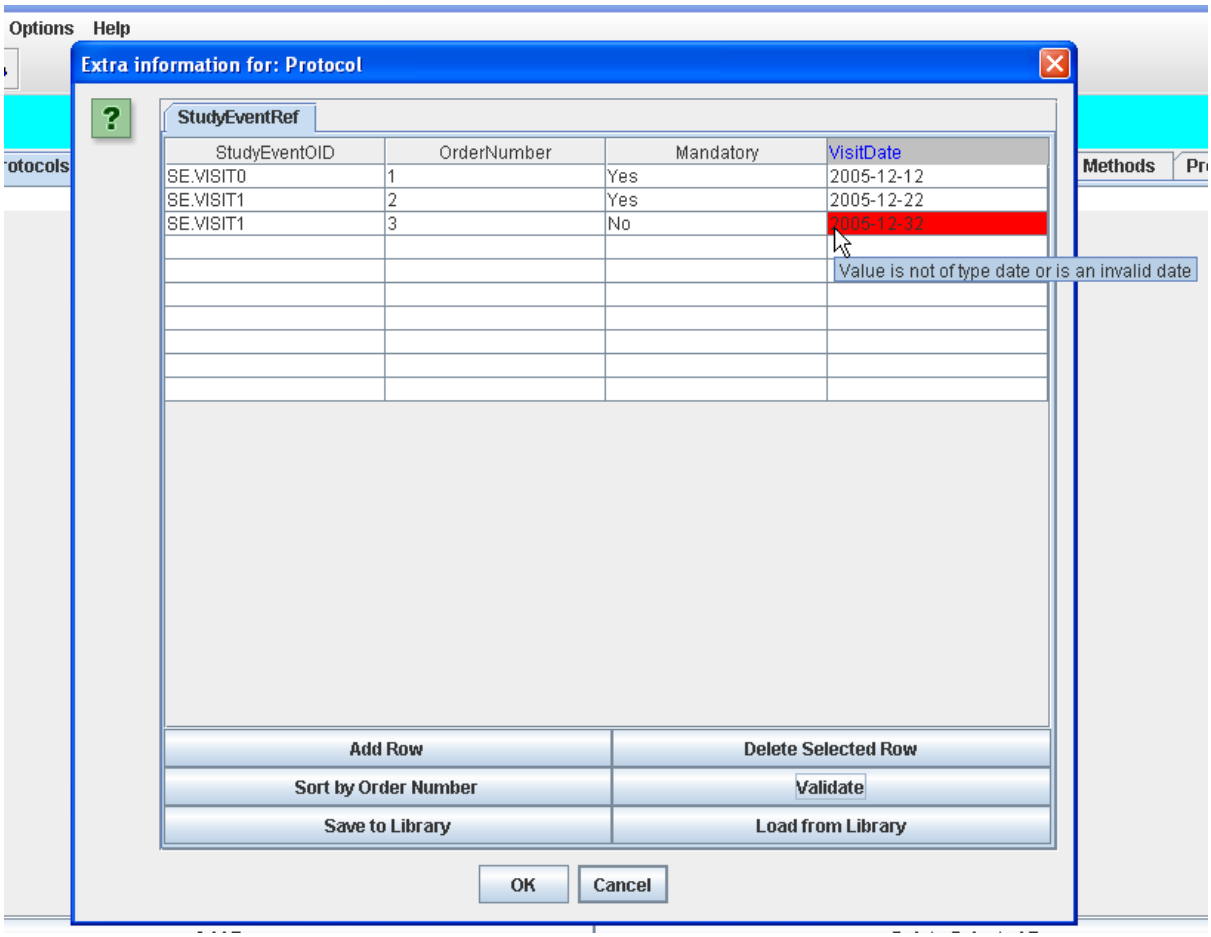
Many dialogs and wizards for fast generation and selection of Forms, ItemGroups, Items, Codelists and so on ...

The ODM Study Designer: screenshots



SDTM ready: a dialog to choose a Domain for an ItemGroup

The ODM Study Designer: screenshots



Full and automatic support of Vendor Extensions:
an example of a Vendor Extension allowing Visit Date Scheduling.
The date 2005-12-32 is not a valid date.