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CDISC International Interchange Bethesda

CDISC is holding its yearly International Interchange Conference in Bethesda (near Washington D.C.) from October 1 to 5, at the Marriott Besthesda North Hotel Conference Center.

From a modest two-day conference, the Interchange has grown to a five-day event, with workshops, trainings, and for the first time, parallel sessions.

The first day, Monday October 1st, is dedicated to the “end-to-end” workshop to which XML4Pharma will contribute (see below). This is a repeat (but of course showing the latest progress) of the very successful “end-to-end” workshop of the European Interchange in May.

Day 2 and 3 sees the conference itself, this time with a number of parallel sessions. The reason for this is that CDISC and its activities have grown to such an extent, that it is not possible anymore to discuss all aspects of the CDISC standards in the usual way in only two days. Unfortunately (in my opinion), the organizers have chosen to have sessions by CDISC model (ODM, SDTM, CT, ...) whereas integration of all these models is currently one of the top priorities of CDISC.

On Thursday, there will be a workshop on “Legacy data conversion”, and different implementation workshops (SDTM, SEND, Lab). The SDTM implementation workshop is continued on Friday, when there is also an ODM implementation workshop.



Full information, including registration information can be found on the [CDISC website](http://www.cdisc.org).

XML4Pharma at the CDISC Interchange

Of course, we will also be present at the october Interchange, and contribute to this event.

First of all, we will contribute to the “end-to-end” workshop on Monday, where we will report on the progress of a standardized XML-representation for Trial Design (developed for CDISC as an ODM-extension), and where we will also demonstrate our SDTM-ETL™ software, for the development and execution of mappings between ODM and SDTM.

On the first day of the conference, we will give a presentation with the title “ODM seeks SDTM – the missing link revisited”. This presentation will learn how ODM and SDTM can be linked together (within the end-to-end idea). Best practices such as “study design with SDTM in mind” and “using CDISC Controlled Terminology in ODM study design” will be extensively discussed. Also, we will demonstrate how the SDTM-ETL™ software fits perfectly into the the end-to-end idea (the “missing link”).

SDTM-ETL™ 1.1 now available

Version 1.1 of the SDTM-ETL™ is now available. A lot of new features have been added, this on request of some of our customers. The most important new features are:

- optional output in SAS Transport format (XPT)
- Creation of additional, non-standard SDTM variables as described by the rules in the SDTM IG v.3.1.1
- Full CDISC Controlled Terminology implemented as define.xml CodeLists: Package 1 / Lab Test Codes and SDTM Package 2A

This will however not be the end of further development of the software, as also the CDISC standards evolve and integrate more and more with each other.

For example, the new SDTM 1.2 Standard and its new Implementation Guide (SDTM-IG 3.1.2), recently published for public review, contain many improvements and some new domains and variables. This means that in future (when the SDTM 1.2 becomes “final”) users of the SDTM-ETL™

software will have the choice between two versions of the SDTM to work with.

Furthermore, a CDISC team is currently working on a format (ODM-based) for submitting SDTM data as XML. This at the same time means that there will be an update of define.xml.

Once these ready, we will implement both in the software. The current version of SDTM-ETL™ does already have an SDTM-XML export, which is an early prototype of the SDTM-XML standard currently developed by CDISC.

All necessary information about version 1.1 of SDTM-ETL™ is available at:
www.XML4Pharma.com/SDTM-ETL/index.html

CDISC publishes SDTM 1.2 and SDTM-IG 3.1.2 for public review

CDISC recently published version 1.2 of the SDTM standard for public review. At the same time also the corresponding Implementation Guide (v.3.1.2) has been published (also for public review). The proposed documents can be downloaded from the [CDISC website](#).

Additionally, an appendix (draft) to the existing Implementation Guide (v.3.1.1) - “[MetaData Submission Guidelines](#)” has been published. It contains a set of sample submission files and a PDF document containing the guidelines.

I haven't read the whole document yet, but some sections nicely explain the relation between what is in the define.xml file and what is in the submission datasets (currently in SAS transport format). Furthermore, it nicely explains how CRFs should be annotated with SDTM information.

Comments to these draft versions of SDTM 1.2, SDTM-IG 3.1.2 and the “Metadata Submission Guidelines” distribution should be send to CDISC no later than September 28.

FDA launches pilot to submit CRFs in ODM format

In March, the FDA launched an initiative, inviting sponsors to take a part in a pilot for the submission of CRFs in XML-ODM format. In this pilot, selected sponsors will need to as well provide the CRFs as PDF files, as as ODM files.

The goal of the FDA is to gain experience with (e)CRFs in XML format. The advantage for the sponsors would be that, once the agency accepts ODM files, the sponsors would not need to transform every eCRF (from EDC) into PDF format.

Of course, this will require the FDA to be able to view and inspect CDISC ODM files in a user-

friendly way, which may require the development of software tools.

We do already have (for many years) such software tools. One example is our [CDISC ODM Viewer](#). It is used by a good number of companies to inspect their ODM files, and to generate custom reports in as well HTML as PDF.

An [evaluation version](#) of the CDISC ODM Viewer can be downloaded from our website.

Furthermore, our [demo application at the XML4PharmaServer](#), which generates eCRFs on the fly from study definitions in ODM format, nicely demonstrates how, when a filled eCRF is submitted to the server, the data are stored as ODM in the database, and at the same time, a PDF representation of the submitted eCRF is generated (see a picture at the end of this newsletter).

The FDA announcement about the ODM pilot can be found [here](#).

CDISC Controlled Terminology

Also recently, CDISC published “SDTM Package-1 & Lab Test Controlled Terminology” (for implementation – so “final”). Also package 2A was recently published for public review. The latter contains controlled terminology for measurement units, for ECG, and for dosing frequencies (as used in SDTM domains CM, EX and SU).

As we strongly believe that CDISC controlled terminology must be easily implementable in ODM and in define.xml, we immediately transformed the published terminologies (which come as Excel worksheets) into ODM/define.xml CodeLists, and implemented these in our applications, such as the [ODM Designer](#) and the [SDTM-ETL™ software](#).

For techies: XForms, Ajax and dojo widgets

Frequent readers of this newsletter know that we advocate the use of XForms, the W3C standard for web forms, for already many years. XForms are now used by companies like Cisco, Xerox, Volkswagen, CSC, Electricité de France, CERN, and all major financial institutes. Only in clinical research, the use of XForms is still very limited (well, this is a conservative industry).

The raise of **Ajax technologies** (Asynchronous JavaScript and XML) during the last year has led to a strong increase of XForms implementations that user server-side technology (as an alternative to browser plugins, such as for [Firefox](#) or [Internet Explorer](#)).

Now, one of the difficulties with such Ajax-based

XForms implementations is that user-friendly widgets need to be developed. For example, when the user needs to enter a date, a Calendar widget should pop up, so that the date can be entered just by clicking, without any typing, and so that it becomes impossible to enter an invalid or badly formatted date.

The Calendar example is the most simple one, but what about entering a time, or even more difficult, a duration? For durations, there is an international standard (ISO 8601). For example, 1 month, 3 days, 7 hours and 12 minutes is expressed as P1M3DT7H12M. Now, one can not expect a user to enter this by hand (i.e. typing), so a user-friendly widget is necessary. Not all XForms implementations do however have a very extensive sets of such widgets yet (well, but IE hasn't got it either).

A major step forward has now however be made, as a new extensible toolkit for Ajax widgets has now been published. The Dojo toolkit team has completely revised its Ajax toolkit, and has now published Dojo 0.9. As this toolkit is completely modular, new widgets can easily be developed from the base widgets, and implemented in any Ajax-based web application.

Major XForms implementors, such as [Chiba-web](#), have already announced that they will implement Dojo 0.9 in their next version, in such a way, that XForms implementers can further extend (and customize) the set of widgets for use in their own applications.

This is surely what we intend to do in our demo application demonstrating [the use of XForms in EDC](#).

First German-speaking CDISC User Meeting

If you read this on Monday (Sept.24), you just have the time to jump on the train or take the plane, as on Tuesday, September 25, the first German-speaking CDISC User Meeting takes place in Berlin, in the wonderful Langenbeck-Virchow-Haus.

We will be giving a presentation during this meeting titled "CDISC Ausblick: Weitere Entwicklung und Konvergenz der CDISC Standards SDTM, ODM und Co." ("CDISC Roadmap Outline: Further development and convergence of CDISC Standards SDTM, ODM and Co.").

The full invitation and program can be found [here](#).

CDISC eCRF example delivered by **XML4Pharma**

Question	Response	Question code	Response code
Visit Date	2007-02-18+01:00	L_VISIT	
Visit Start Time	14:18:32	L_VISITTIME	

Group: Adverse events

Group code: IG_AE_OCCURRED

Question	Response	Question code	Response code
Has the subject experienced any adverse events	Yes	L_AE_OCCURRED	1

Group: Adverse events

Group code: IG_AE

Question	Response	Question code	Response code
Event No.	1	L_AE_EVENT	
Adverse event	Headache	L_AE_TERM	
Start Date	2007-09-21	L_AE_START	
Is the adverse event still continuing	Yes	L_AE_CONTINUES	1
Was event serious	No	L_AE_SERIOUS	0
Is there a reasonable possibility that	Yes	L_AE_RELATED	1