

**Bimonthly newsletter of XML4Pharma,
Schlossbergstrasse 20, DE-78224 Singen, Germany
Phone: +49 7731 975044
Web : www.XML4Pharma.com
Mail: Info@XML4Pharma.com
November-December 2007**



CDISC International Interchange Bethesda

The CDISC International Interchange was a very successful meeting. It had a record number of participants and a very high quality of the presentations and the discussions.

The first day was devoted to a number of workshops, one of which we were also involved (see further). The second and third day then saw the actual conference. As the number of topics and presentations has considerably increased (as CDISC is widening the scope of its activities), parallel sessions were necessary. Somehow this is a pity, as it sometimes occurs that two very interesting presentations take place at the same time.

Thursday was then devoted to another set of workshops and courses. Personally, I attended the EHR-CDISC Integration meeting, and the Legacy Data Conversion workshop. The last day, Friday, was then devoted to the ODM course and the continuation of the SDTM course.

During the conference, I gave a presentation titled "ODM seeks SDTM – The missing link revisited". This presentation was about how SDTM information can be added right from the start to the study design, and how mapping between ODM and SDTM can be designed and executed. It also presented the main features of the SDTM-ETL® software (see further).

The slides from all the presentations can be found on the [CDISC website](#).

Also the commercial exhibition was very interesting. As I did not have a booth myself this time, I had the opportunity to talk to many people, and to establish a lot of new contacts.

Award !

At the CDISC Interchange, and to my great surprise, I was awarded (among a good number of other CDISC volunteers) the "Super Performance" award ("In appreciation of your Outstanding Contributions to the CDISC Mission in 2007"). Other members of the CDISC ODM team that received the award were Tony Friebel (our XML-schema specialist – from SAS), and Kevin Burges (our EDC specialist – from Formedix).

Well, I am pretty proud about this!

A picture of the award can be found at the end of this newsletter.

David Iberson-Hurst joining the CDISC organization

At the Interchange, it was also made public that David Iberson-Hurst is joining the CDISC organization as VP of Technical Strategy.

Dave is a long-time member of the ODM Team and since about a year its team leader. He and his company Assero are pioneers in implementation of ODM, and especially in ODM Compliance and 21CFR Part 11 issues. Dave also talks a lot to the FDA, and is the person who convinced them to start working with the ODM (see our previous newsletter).

Dave's assignment as VP Technical Strategy also means a further professionalization of the CDISC organization: whereas about 3 years ago, CDISC had only 3 full-time people on the payroll, this number has now increased to about 10.

CDISC SEND group reestablished – FDA pilot

Another good news from the CDISC Interchange is that the SEND group has regrouped and is now again "life and kicking". The team is led by Lou Ann Kramer from Lilly, and now has about 10-20 volunteers (with several subteams). They had a first face-to-face meeting and now have regular teleconferences.

Very encouraging news is also that a SEND pilot has been started at the FDA. During the pilot, pharma companies can submit non-clinical data in SEND format in parallel with the usual PDFs.

Information about this pilot can be found on the [FDA website](#).

German speaking CDISC User Group

A few days before flying to the CDISC International Interchange in Bethesda (near Washington), I was at the inaugural meeting of the German Speaking CDISC User Group in Berlin.

[TMF e.V.](#) (Telematikplattform für Medizinische Forschungsnetze) was so kind to host this first meeting and to set up the practical organization. Many thanks to Mr. Drepper, Mr. Sendler and Mrs. Jacobi!

After the welcome words from Tim Jaeger (representing the E3C: European CDISC Coordination Committee - Roche) and Ann-Sofie Bergström (representing the CDISC European Users Groups – SAS) and a short introduction from Mr. Drepper and Mr. Senler, Rolf Meinert ([KKS Mainz](#)) and Johannes Hüsing ([KKS Heidelberg](#)) gave presentations libraries of SAS macros for use with CDISC SDTM, and on the use of the SDTMWandler software. I then gave a presentation about the CDISC Roadmap and the integration of the different CDISC standards.

After an excellent lunch, Daniel Rehn (Roche) took the lead in the discussions about how to set up the German speaking users group. One of his proposals was to set up an internet forum (which can now be found [here](#)). There was a lot of discussion about how regular the group should meet, and whether it should or should not be combined with the European CDISC Interchange.

The participation to this first user meeting was unexpectedly very high: about 50 people from Germany and Switzerland participated. One of the challenges of the group will also be to get more people from Austria involved.

A report of the meeting can be found on the [CDISC website](#).

EHR – CDISC Integration demo available

One of the “hot” topics currently at CDISC is the integration with EHR (Electronic Health Records): in most hospitals, clinical researchers have to copy information that is already available in the hospital patient information system in the form of electronic health records, into the (e)CRFs. This does not only make life of investigators more difficult, it is also a potential source for errors.

Landen Bain of CDISC did set up an initiative already a number of years ago to investigate and to demonstrate the ability of integration between EHRs and CDISC standards, culminating in a large operability demo at the [HIMSS 2007 Conference](#) with over 10 companies involved.

The profile used at HIMSS (RFD: Retrieve Form for Data Capture) uses **XForms** as the forms technology. The advantage of using XForms is that it is an [open W3C standard](#), for which already a good number of browsers, browser-plugins and

server implementations is available. Furthermore, as it is an open standard, the forms are portable, meaning that (at least when the EDC vendor supports the standard), they can be ported from one EDC system to another.

As we do already advocate the use of XForms for a number of years, we decided to develop a [small demo application on our demo application server](#) that demonstrates how information from a hospital patient information system can be used in EDC.

The demo application, has an entry screen which emulates the hospital information system. When the user (investigator) selects to request the information of a patient, the information is retrieved from the hospital information system, and it is indicated whether the patient is involved in a clinical study, and if so, a list of the available forms for that study is shown. When the user then selects the form, it is retrieved from the EDC system and prepopulated with information from the hospital information system.

The user can then fill the remaining fields in the form and submit the form to the EDC system. The latter then transforms the content from the submitted form to CDISC ODM, and also generates a PDF file for the archive of the investigator.

The screenshot displays a web-based form with the following sections and fields:

- Study Event ID:** BL_VISIT
- Group: Common:**
 - Site number*: 12
 - Subject ID*: S025
 - Visit Date*: 2007-11-29
 - Visit Start Time*: 15:32:05
- Group: Demographics:**
 - Date of Birth*: 1960-03-11
 - Sex*: Male
 - Race: (dropdown menu)
- Group: Smoking History:**
 - Check when the subject is a smoker*:
 - Number of cigarettes per day*: (dropdown menu)

The prepopulated eCRF

The demo application can be tried out on our [demo application server](#).

CDISC ODM and Internationalization

Also on our demo application server, one can now find an example ODM file demonstrating the internationalization (i18n) and Localization (l10n) capabilities of the ODM 1.3 standard. The example ODM file contains a study setup with all forms, questions and codelists in as well the english, french, german and korean language. A special thanks here to prof. Inyoung Choi ([the Catholic University of Korea](#), College of Medicine, Department of Preventive Medicine), for providing the Korean translations and adding them to the ODM file.

This very internationalized ODM file can then be used to automatically generate eCRFs (in XForms format) in any of the mentioned languages, to fill these forms, and to submit them to the server where they are transformed in ODM clinical data and in PDF for the investigators archive.

Group: 일반사항

기관번호 [redacted]
시험자ID [redacted]
방문일자 2007-11-29
방문시간 16:23:38

Group: 혈액학적 검사

검사명 [redacted]
검사번호 [redacted]
고유번호 [redacted]

시행하지 않은 경우 체크하세요

The "Laboratory" eCRF in the Korean language

SDTM-ETL™ demo at CDISC Interchange

As part of the end-to-end workshop at the CDISC Interchange in Bethesda, we gave a demo about how clinical data (in ODM format) can be transformed in SDTM datasets using the SDTM-ETL® software.

We showed how operational data can be mapped to the Physical Exam (PE) and Vital Signs (VS) SDTM domains, and how this mapping can be executed to obtain SDTM datasets in SAS Transport format, and how at the same time, the full define.xml is automatically generated.

STUDYID	DOMAIN	USUBJID	PESEQ	PE.PESEQ	PE.PETESTCD	PE.PETEST	PE.PE
MyStudy	PE	001	1	1	1	Head, Neck and Th	Normal
MyStudy	PE	001	2	2	2	Eyes, Ears, Nose a	Normal
MyStudy	PE	001	3	3	3	Chest	Normal
MyStudy	PE	001	4	4	4	Lungs	Abnormal
MyStudy	PE	001	5	5	5	Heart	Abnormal
MyStudy	PE	001	6	6	6	Lymph Nodes	Abnormal
MyStudy	PE	001	7	7	7	Abdomen	Normal
MyStudy	PE	001	8	8	8	Anorectal	Not Done
MyStudy	PE	001	9	9	9	Genitalia	Normal
MyStudy	PE	001	10	10	10	Skin	Abnormal
MyStudy	PE	001	11	11	11	Musculoskeletal	Normal

[All information about the SDTM-ETL® software can be found on our website.](#) A flyer as well as a brochure can be downloaded. For seriously interested parties, also a full tutorial, demonstrating most of the features of the software, can be obtained on request.

CDISC European Interchange 2008

The "US" CDISC Interchange has just passed, and the announcement for the next European Interchange is already out !

The next European Interchange will take place in Copenhagen (Denmark) from April 21 to April 25 at the Marriott Hotel in the center of the city.

Workshops and training will take place on Monday, Tuesday and Friday, with the main conference on Wednesday and Thursday.

Copenhagen is a beautiful place to be, but with all the exciting events during the Interchange, you better already reserve the weekend before or after, as there will be ample time to visit the city during the conference itself !

Fast Track receives ODM Certification

[Fast Track Systems](#), with headquarters near Philadelphia, is now the third vendor that received ODM certification from CDISC, for its TrialSpace Designer software product. The TrialSpace Designer is a protocol design software, that can export trial designs in CDISC-compliant ODM format.

People from Fast Track are also closely involved in the CDISC "Trial Design Model" working group, for which an XML-based implementation standard is envisaged for the not-too-far future.

Previous companies that received ODM certification from CDISC are [ClinPhone](#) and [XClinical](#).

The interest for ODM certification is strongly growing. So one should not be surprised when one or two more EDC vendors also obtain the ODM certification before the end of the year.

X-Smiles releases version 1.0 of its XForms browser

The number of XForms browsers, browser-plugins and server side implementations is rapidly growing. Large companies like IBM have embraced the technology and are putting resources into integrating XForms technology in their systems and products.

X-Smiles was one of the earliest standalone browsers that supported (part of) the XForms standard. It is a development from the “Telecommunications Software and Multimedia Laboratory” (TML) at the [Helsinki University of Technology](#) (Finland).

The group has now released version 1.0 of the browser, which also supports [SMIL](#), a W3C standard for multimedia.

The X-Smiles browser promises support for XForms for any Java VM (including J2ME Personal Profile). It has been implemented not only on Windows, Linux and Mac systems, but also on mobile devices like Nokia Communicator, Compac IPAQ,

Also a Java applet and Java WebStart implementation are available.

I haven't found the time yet to thoroughly test this new XForms browser, but a very first quick test on some of my eCRFs gave excellent results.

The only thing I did not like so much was the presentation, but this can very probably be improved by changing the CSS stylesheet.

Line Number
a

Medication For Conmed
Aspirin

Exact start date is
known

Start Date
November 27, 2007

Ongoing
No

Exact stop date is
known

Stop Date
November 29, 2007

Calendar widget showing November 2007.

The X-Smiles browser in action using an Adverse Event eCRF

The X-Smiles browser in action using an Adverse Event eCRF

DataSci strikes again!

DataSci, an EDC company that produces nothing at all, except for lawsuits, has hit again. The latest “victim” is eTrials, that pays DataSci a sum of \$1.75 million to settle DataSci's lawsuit. DataSci is a company that successfully obtained a US Patent that claims the use of the internet for use in electronic data collection. Well, maybe I should try to patent the “use of cars to drive to the supermarket”, and then collect money from everyone who actually uses his car to drive to the supermarket.

