Bimonthly newsletter of XML4Pharma,
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XML4Pharma is a CDISC Registered Solutions Provider

SDTM-ETL™ v.2.0 is out!

We are currently rolling out v.2.0 of our famous and popular software for setting up and executing mappings between operation clinical data (CDISC ODM) and SDTM or SEND data.

Highlights of the new version are:

- full support for Trial Design data sets, with semi-automatic mapping from trial design SDM-XML information (the new ODM-based standard for trial design information)
- Full support for Amendment 1 to the SDTM v.1.2 and SDTM-IG 3.1.2
- new color schemes for "required", "expected" and "permissible" variables
- newest CDISC controlled terminology
- incorporation of the newest version (1.2.1) of OpenCDISC
- direct access to the corresponding page of the SDTM-IG or SEND-IG, or SDTM standards document
- many more feature improvements, such as codelist generation from important "MeasurementUnit" definitions

Version 2.0 is surely a milestone version of the software, and we are proud that we can now present it to the community.

More information about v.2.0 of SDTM-ETL™ is available on our website at: http://www.XML4Pharma.com/SDTM-ETL.

CDISC Journal: our article

The first issue of the CDISC Journal is now available on the CDISC website.

In this first issue, you can find our article "Generating a caBIG Patient Study Calendar from a Study Design in ODM with Study Design Model Extension".

The article describes our work to use the new SDM-XML standard to generate instances of the caBIG PSC, which is used a lot in cancer studies. It describes the similarities and differences of both models and how one can transform an ODM-SDM-XML based study design into XML that can be read by the PSC software to generate a study calendar for a group of patients.

Two new blogs

In order to structure my own thoughts on several CDISC matters and share them with the community, I recently started two blogs. You can find them at:

- http://cdiscguru.blogspot.com/
- http://cdisc-end-to-end.blogspot.com/

The first is about general CDISC matters, such as announcements. For example, it discusses new questions raised by "Amendment 1 to SDTM 1.2 and SDTM-IG 3.1.2".

The second is more specific and is about CDISC end-to-end, and how it can technically be realized. This has of course to do with ODM, with define.xml and especially with a new envisaged XML-format for exchange of submission (SDTM/SEND) data in XML.

Of course you can add comments to my entries in these blogs.

HL7 training course

I have recently started a HL7 eLearning course, organized by HL7 Austria, which hopefully will lead me to become HL7-certified. I do this in my role as a professor in Medical Informatics at the University of Graz. This training will further improve my understanding of and expertise in CDA, which I need to lead several projects at the university. The reason is that Austria has decided to base its national EHR System (ELGA), and we have many student projects that use CDA documents, such as the Austrian version of the "Continuity of Care Document".

Some of you may be surprised by this, as I may be known to some of you as being pretty critical to HL7-v3, on which CDA is based. My criticism is however mainly on the HL7-v3 messages, to which CDA does not belong. But I am also pretty critical to the way HL7-v3 has been implemented in XML.

Becoming an HL7 expert, however hopefully allows me to contribute to improvements from within the organization itself ("if you can't beat them, join them"), and for example to contribute to a successor of version 3. visits datasets (can't their tools do that?)

Wayne Kubick is the new CDISC CTO

CDISC could not have made a better choice: it appointed Wayne Kubick, one of the real CDISC veterans and volunteer since the very beginning, as the new Chief Technology Officer (CTO). Congratulations Wayne!

Wayne is not only one of the main contributors to the SDTM standard and its implementation guides, but he also has a solid techical background, and an extremely good and deep knowledge of all the CDISC standards.

I do know Wayne personally for many years, and what I especially admire in him, is his humorfull way to analyze and criticize the conservatism in our industry (among others). I remember several presentations of him at conferences where he critically analyzed the use of the XPT format for use in submissions, and the crazy idea to replace it by HL7-messages, but in such a humorful way that noone got the feeling to be criticized. This sense of humor and his diplomacy allows him to be a welcome guest at the highest levels of the FDA, allowing him to use his influence to gently force the agency into modernizing their ancient IT systems, and into making the right IT decisions.

Having been a CDISC volunteer himself for very many years, Wayne is the ideal person to lead and guide the many volunteer development teams, aligning their work, and taking care that all our standards work together.

I wish Wayne all the best in his new position!

A student's project: automated generation of SDTM databases for FDA-CDER

Our Bachelor students need to complete two larger projects during their three year term. Our second-year students will soon start working on their first project in small groups (about 3 students per team). The projects they will be working on this year are in the area of electronic health records, primary and secondary use. One of the projects is however about designing and developing a software systems that automatically generates a relational database starting from any (conformant) set of SDTM datasets together with its accompanying define.xml file.

The idea is that the define.xml is essentially a blueprint for a database, thus allowing to automatically generate a complete set of ANSI-SQL "CREATE TABLE" statements, including assignment of all the keys and of foreign keys. The SDTM datasets themselves (currently in SAS XPT format) can then automatically be transfored into SQL "INSERT" statements and so populate the database.

When successful, we envisage to donate the software to the FDA, as we do know that e.g. CDER does currently not have the necessary technical knowledge to automatically generate databases from SDTM submissions.

CDISC publishes draft standard for SDTM Device Domains

CDISC just released the draft version of the "Device Supplement to the Study Data Tabulation Model Implementation Guide", essentially an extension to the SDTM for devices such as implants.

This supplement defines 6 new domains: Device Identifiers (DI), Device In-Use (DU), Device Exposure (DX), Device Events (DE), Tracking and Disposition (DT) and Device-Subject Relationship (DR).

We are currently reading through the draft document (which can be downloaded from the CDISC website), and will probably come with some comments in the next issue of this newsletter.

Cool Technology: XForms on the tablet

Browsers are out, apps are in!
Young people use their smartphone more than their home computer. Once again, the IT world is revolutionizing.

Therefore I was positively surprised that already a number of XForm apps are available for use on either smartphone or tablet computer.

Although I do have some doubts about the use of smartphones for doing clinical research by investigators (for the patients however, they are ideal e.g. for diaries), I am convinced that the use of tablet computers is the next step-to-go in clinical research. We do already see that doctors in hospitals use tablets for direct feeding the hospital information system (HIS) with data, and for obtaining patient information from the HIS. In my opinion, tablets can be real "enablers" for single-source and for automatically populating eCRFs from data from the HIS and the patient's health record.

I am currently looking into the different "XForms apps" and hope to be able to report on my findings in the next issue of this newsletter.

CDISC European Interchange Stockholm

I am also very proud to be able to announce that my abstract "Multipurpose usage of the new Study Design Model in XML standard" has been accepted for a presentation at the next CDISC European Interchange in Stockholm in april. I submitted the abstract in my role of professor at the "University of Applied Sciences" in Graz, as the university is strongly supporting me to continue my volunteer work for CDISC.

A preliminary program has also been published now: as usual there are two pre- and one post-day of trainings, with the main conference taking place on Wednesday and Thurday. For more information and registration, please visit: http://www.cdisc.org/interchange.

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