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XML4Pharma is a CDISC Registered Solutions Provider

Happy New Year!

A happy new year to all our readers.
We wish you a good health in 2011 (and beyond) with a lot of satisfaction in both your professional work and your personal life.

Also in 2011 we will publish news from the CDISC front, and about our activities within CDISC.
Of course there will also be product announcements, such as for the new version 1.5 of our SDTM-ETL™ software already in this issue.

Comments on our articles are always welcome. The easiest is to send them by e-mail to us.

Also, if you like this newsletter, please feel free to forward it to your colleagues. If they like it too, they can also subscribe by just simply sending me an e-mail with their coordinates.

SDTM-ETL™ v.1.5 released

We just released v.1.5 of our popular SDTM-ETL™ software. The new version now also has an early implementation of the SEND 3.0 standard (which is currently in draft at CDISC), but also a set of new features such as automated generation of "Comments" domains (CO.xpt) with automated splitting into different "COVALn" fields when necessary.

The SEND 3.0 implementation comes as a template file, so that once the SEND 3.0 specification becomes final, we just need to send a new template file to the users.

As the SDTM-ETL™ software is very modular, we could also easily start with the creation of special versions that support vendor-specific extensions to the ODM standard, such as e.g. being used by OpenClinica.

Further extensions for other "vendor" extensions to the ODM will soon be developed. Customers can however also ask to get a version with support for specific "vendor" extensions that they use.

More information about v.1.5 of the SDTM-ETLTM software is available on our website. A "New Features" document can also be downloaded from this site.

SDTM-ETL™ for OpenClinica Users

OpenClinica[1] is a very popular EDC system (as it is free, and open-source) used by many especially smaller CROs and by academic institutions.

OpenClinica has a very good export (metadata and clinical data) and uses some "vendor" extensions to the ODM. So in order to support these CROs that work with OpenClinica, we created a special version of the SDTM-ETL software which fully supports all OpenClinica extensions (starting from OpenClinica 3.0). We named it "SDTM-ETL for OpenClinica Users".

More information about this special version of the SDTM-ETL software is available on our website.

XML4Pharma at the DIA Euromeeting Geneva

We have been invited to give a presentation at the DIA Annual Euromeeting which takes place in Geneva (Switzerland) from March 28 to 30.

1 OpenClinica is a trademark of Akaza Research LLC in the United States and other countries

Our presentation will be on Wednesday morning (March 21) in the session "Practical Implementations of the CDISC Standards", and will be titled "***Almost There: CDISC end-to-end using one standards set and one format***".

The presentation will not only be about the new Study Design Model (SDM - an extension to the ODM standard) and the opportunities it creates, but it will also present a concept based on define.xml/ODM for exchange of submission data (and possibly future submissions to the FDA) , i.e. of SDTM and SEND data. This as the ODM with its current extensions (define.xml and SDM) is also an excellent format to exchange submission data between partners (including the FDA). This contrarary to an HL7-v3 message that is envisaged (but it doesn't work ...) by some at the FDA for the future.

For example, we will present our first ideas about how the ODM can port SHARE information, and how this nicely matches with SDTM and SEND.

What struck me about the meeting's programm cover is that it depicts the Matterhorn (Mont Cervin). As a passionate mountaineer, I know that this mountain is not visible at all from Geneva. When the weather is fine however, one has a beautiful view on the Mont Blanc (the highest mountain of the Alps with 4810m) from Geneva. Probably, Mont Blanc is just not spectacular enough for the organizers to make it to the cover page ...

CDISC German-speaking User Group Meeting

The 10th German-speaking CDISC User Group Meeting will take place in Munich at Kendle, reasonably probably on Monday March 14th.

The main theme will be SDTM mapping with the emphasis on experiences (and especially problems encountered) when mapping clinical studies to the SDTM standard.

The committee is currently hard working on a programm, and proposals for presentations are still very welcome.

People that are on the UG meeting mailing list will get an invitation soon. If you are not on the mailing list, keep an eye of the UG's site.

The future of the ODM standard

From time to time, rumors pop up that ODM will evolve into, or be superseded by an HL7-message. **This is not the case at all**. There are currently no plans at all to replace the ODM by an HL7-message. At the contrary, the ODM Team is now already thinking about the user requirements for v.1.4, about support for SHARE, and even about the possibility of porting submission data (SDTM / SEND).

The team will soon publish the "Study Design Model" (SDM) extension for public review, which will be another milestone for CDISC. Our own "XML4Pharma Study Designer" will support the SDM-extension as soon as it becomes publicly available (see our previous issue).

The not-yet-existing HL7-message(s) for submissions to the FDA is a idea (I call it a "chimera") of some "politicians" (not having any XML knowledge at all) who heard about HL7-messages for electronic health records, and thus incorrectly deduced that it helps the FDA to obtain submissions in HL7 format in order to have better integration with electronic health records.
I did already write an extensive article about this in the past. Very early prototypes of a "study design" HL7-message have been created by a developer paid by the FDA, and were find to have major design errors, such as non-compliance with BRIDG, and mixing up of study design with study excecution. Furthermore, as well CBER as CDER have declared that they are not ready at all yet (will they ever be?) to accept data in HL7-XML format.

But let me share some thoughts about the future of the ODM. These thoughts are **my personal opinion** and not necessarilly those of the ODM development team.

What I see for a future ODM is the following:

- replacement of "StudyEvent" by "Activity" (or similar): the "Study Design Model" as implemented in the ODM-extension already has the concept of "Activity" (or "Study Encounter"). An activity can be a visit, but is not necessarilly so. A subject can also perform an activity which has to do with the study without the presence of an investigator (e.g. filling out an ePRO form). Some activities do not involve data collection at all, such as administering medication. Essentially, a visit is just a kind of activity (or "Study Encounter"). Putting "visit" on the same level as "activity" (using the same XML name for it?) will make it easier to define workflows.
- recursive activities: activities can have "sub-activities", so an activity can have an internal workflow. A visit (as an activity) can have its own set of sub-activities with its own

workflow. So recursiveness in activities is surely we something want to have, especially in order to have better integration with hospitality planning and information systems.

- SDM becoming core ODM: the "Study Design Model" (SDM) has been created as an extension to the ODM standard, but in my personal opinion, it should grow into the core ODM, this as essentially, the core ODM (or at least part of it), is about study design after all. This is something I already wanted to have for many many years, and I think this is the right moment to start thinking about how this can be accomplished.
- support for carrying submission data: at least 4 technology vendors are already using ODM now for keeping submission (SDTM) data in their applications. The advantages are clear: no 8-, 40- or 200-characters limitations, no SUPPQUAL necessary, no COMMENTS nor RELREC data sets necessary. Just by using existing ODM constructs, such information can be kept close to where it belongs, i.e. at the data point itself.
- support for SHARE: some of the SHARE concepts are already present in the ODM. For example the idea that the unit of measurement is an attribute to the data point itself rather than another field in the record (as in SDTM). Once SHARE is more mature, I believe we should start working on supporting it in ODM.

Cool Technology: Open Data Kit (ODK)

I am always looking for new cool technology that can be used in clinical research. Very recently, I found "Open Data Kit" which is a set of software tools for data collection, aggregation and vizualisation. It has been developed by the University of Washington for data collection (especially for medical information) in developing countries where computers are rare, but mobile phones are usually the best way of communication.

The data collection module is named ODK Collect and is essentially an implementation of XForms for Android-based mobile phones.

As we do already have the technology to transform CDISC ODM study designs into XForms forms, ODK Collect could also easily be used in clinical research, e.g. in ePRO.

Cool features of ODK Collect are that it can also collect the GPS position, and can record voice, images and video. So when a subject experiences e.g. an eczema skin allergic reaction as an adverse event, he/she can send a picture of the eczema together with the adverse event record.

If I find the time, I will test this technology for use in clinical research in the next months. I will let the readers know about the results.

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