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

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We are slowly sliding into Winter. Time again to publish a new newsletter

ODM 1.3.1 for review

The ODM team will publish a minor update of the ODM 1.3 standard and XML-Schema in the next few days (v.1.3.1) for public review.

This update corrects some small errors in the previously published specification and XML-Schema, and relaxes some constraints, e.g. to even better support extensions such as the upcoming Trial Design extension.

A number of clarifications and notes about "best practices" have also been added.

As usual, the ODM 1.3.1 is 100% downwards compatible: every valid ODM 1.3 file is also a valid ODM 1.3.1 file.

SDTM-ETL™ v.1.3 final now available

In our previous newsletter, we announced the availability of the beta-version 1.3 of our popular SDTM-ETL software.
The **final** version has now been released and is currently being shipped to our customers.
The new release adds a number of new features, such as non-standard variables (which go into SUPP-- at execution time), and a full implementation of the new SDTM v.1.2[1] (SDTM-IG 3.1.2).
More information about the SDTM-ETL software is available on our website.

SDTM-ETL™ v.1.3 – special offer

As an introduction offer, the SDTM-ETL v.1.3 is now offered with a **20% discount** on the list price if ordered before the end of the current year. This also includes free updates until the end of 2010.

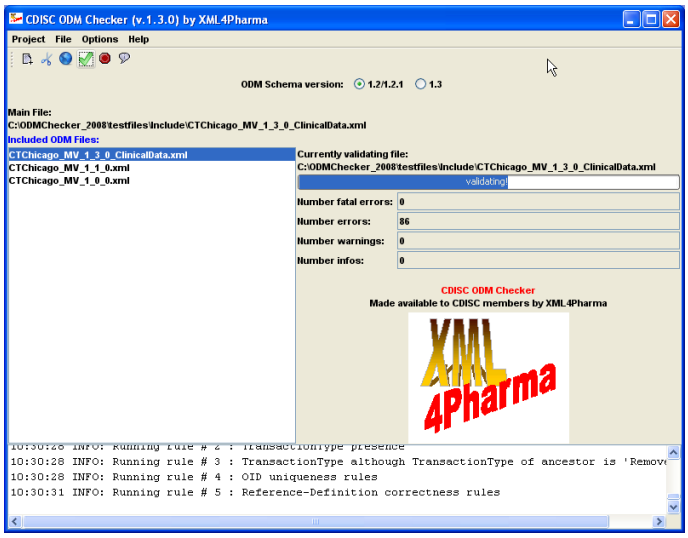
Please send us a short e-mail for more information.

1 As far as we know, our SDTM-ETL software is the first software system implementing the newest version of the SDTM, which was published at the end of last year.

Fully redesigned version of the ODMChecker is now available

A fully redesigned version of the ODMChecker is now freely available for CDISC members and for academic institutions.

This new release also allows to validate ODM 1.3 instance files against the standard[2].



The software has been redesigned in such a way that future versions of the ODM standard can easily be implemented. It has also been concipated so that it can easily be integrated in existing systems and processes of e.g. CROs, EDC vendors and sponsors.

The checker now has extremely good support for the "Include" mechanism for different metadata versions.

Full information about the ODM Checker and its availability can be found on our website.

The ODM Wiki

Some time ago, we have set up an "ODM Wiki" on our website.

We are now rapidly adding new articles to this wiki. Currently the following articles are already available:

2 The old version only allowed validation of ODM 1.2 files

- CDISC ODM in multi-language studies
- The "Include" mechanism in CDISC ODM Study descriptions
- Using RangeChecks in ODM 1.3
- Using Conditions in ODM 1.3
- Annotating ODM with SDTM and CDASH information

The Wiki is "read-only" but people who would like to contribute are cordially invited. Just let us know ..

Akaza Research releases OpenClinica 3.0

OpenClinica 3.0, the open source EDC system has just been released by Akaza Research.

OpenClinica is increasingly popular in not only academic clinical research, but also at smaller CROs that cannot afford an expensive EDC system.

From the point of view of CDISC support, the new release now also allows to export metadata and clinical data in ODM 1.3 format. Furthermore, it allows to import clinical data from external sources into an existing study. The latter however still needs to be setup from Excel worksheets. Import of ODM metadata to automatically setup the system is not yet supported.

ODM, define.xml and XML-Schema 1.1

XML-Schema 1.1 has now nearly achieved the status of "recommendation" by the W3C.

This means that it is fairly stable and that tools for working with this new version of XML-Schema are now being developed by several vendors and foundations. For example, the Apache Foundation does already have an early implementation of Xerces, the popular parser[3], available.

XML-Schema 1.1 is a major step forward relative to version 1.0. I would even dare to state that the step forward is as large as the one when we switched from "Document Type Definitions" (DTD – e.g. used for ODM 1.1) to XML-Schema.
For example, Schema 1.1 allows to define (Schematron-like) rules between elements and attributes that could not be expressed in Schema 1.0.

We (as part of the ODM team) are currently looking into XML-Schema 1.1 for a future version of the ODM standard. As it is quite a good amount of work to extend our current ODM Schema to Schema-1.1, we are looking for support from an academic group (e.g. as a thesis work) to develop a first prototype.

If you are working in academia and are interested in working with us in the development of an XML-Schema 1.1 for ODM, please let us know.

CDISC publishes BRIDG 3.0

CDISC has just release BRIDG 3.0 for public review. The downloads can be found here.

I started with the "User Guide". It is a document that is not easy to read, but I managed to fight myself trough it.

One of the things that is new in BRIDG, and that I like a lot, is that the strong interweaving with the HL7 RIM has been removed: there is now a separate mapping available between BRIDG and the HL7-RIM. One of my critics to BRIDG has always been that it looked as BRIDG is *based* on the HL7-RIM.

I think it is very good that this separation has now been made, as the HL7-RIM is strongly criticized by ontologists to be incorrect from the basis on. Also its XML implementation, HL7-v3-XML is strongly criticized as well by XML specialists ("bad-practice XML", "abuse of XML") as by software architects and developers ("almost impossible to implement, or only at extremely high cost").
The current separation also allows mappings to other (and better) RIMs, such as the OpenEHR RIM.

In my opinion, the next step for CDISC should be that it comes to alliances at the same level as the one with HL7, with other standardization organizations in healthcare such as ASTM (those who have followed the discussions about CCD versus CCR for EHRs[4] know why) and with OpenEHR – and others.

As reported before in our newsletters, we have developed transformation engines in the past to prepopulate CDASH eCRFs with data from as well OpenEHR as from CCD EHRs with good success. So both are equally viable standards for integration with clinical research.

I still need to read a lot of stuff from the BRIDG 3.0 package, and will inform the readers about my progress in the next issue of the Newsletter.

3 Xerces is also the default XML parser for Java

4 Although it seems that (according to HL7) "HL7 CCD = ASTM CCR + HL7 CDA", the reality seems to be different. Currently it looks as the "market" is about evenly divided between HL7 CCD and SDTM CCR, at least in the US. In Europe and Australia, the situation seems to be completely different: more and more countries are moving towards OpenEHR as a choice for exchangable EHRs.

CDISC publishes new Controlled Terminology

CDISC has just published "Controlled Terminology Package 4" for public review. The package contains terminology from 5 teams and areas ("Laboratory Data", "Pharmacokinetic Data", "Microbiology Data", "General Terms" and "ADaM").

The public review period ends Friday November 20, so all those interested in CDISC CT should download the packages right away, and start going over all the terms ...

To me, it is still a bit strange that an "Open Standards" organization publishes standards using a propriety format (MS Excel). So once final, the first thing we will do is to make the new Controlled Terminology available to our customers as ODM/define.xml **CodeList**s (XML), and incorporate the latter in our products (ODM Designer, SDTM-ETL).

OpenEHR starts cooperation with SNOMED-TC

OpenEHR, a standardization organization for Electronic Health Records (EHRs) recently announced a cooperation with IHTSDO, the organization that develops and promotes the use of SNOMED CT.

The goal of the cooperation seems to be the implementation of SNOMED CT in OpenEHRs "archetypes". Geographically the effort seems to be concentrating on Europe, the press release mentioning the "UK Terminology Centre" and the EuroRec institute.

FDA starts accepting SDTM 1.2

According to a recent announcement on the CDISC website, the FDA is now ready to accept SDTM submissions according to version 1.2 of the SDTM standard (SDTM-IG 3.1.2). When following the link to the FDA website however, the latter does not explicitely state version 1.2 nor SDTM-IG 3.1.2. It just provides a link to the ... CDISC SDTM website!

The same page on the FDA website also has another announcement: "FDA intends to begin accepting study data in HL7v3 format" followed by ... "in 2013".

Oh my God! Do we really have to use this stone-age SAS Transport 5 format for at least another 4 years? What a disappointment! And that though we do already have an XML-format for carrying SDTM data for at least 2 years (based on ODM). Why did the FDA refuse to use that?

In view of the critique of leading XML-specialists ("abuse of XML") leading ontologists ("RIM is ontological nonsense"), IT-economists ("extremely expensive to implement"), HL7-v3 is surely not the best format to transport simple 2-dimensional tables[5].

The argument of integration with EHRs is also nonsense: it is not because you use a truck of the same brand as a transporter for as well oranges as for cows, that you can integrate cows with oranges, i.e. produce cows that deliver orange juice.

The pharao and his disease

Another interesting contribution I read on a blog: according to that contribution, HL7 RIM as well as SNOMED CT consider a "disease" as an "observation" or a "finding". Makes sense doesn't it? As long as noone observed the disease it does not exist isn't it?

The blog gives the example of the archaeologist who finds out that an ancient pharao had osteoarthritis. The question now is when the disease came into existence: when the archaeologist found out (so thousands of years after the death of the pharao)? Or was it before the pharao died – although he was never diagnosed for that disease?

Interesting discussions ..., not only for ontologists, but I think also for all who develop models for use in health care.

5 The statement that SDTM will stay as it is now, even with the new HL7-v3-XML format replacing SAS XPT as the transport format, doesn't make sense either: why should a format with 10 layers of deepness be needed to represent two-dimensional tables? If HL7-v3-XML will be used, also the SDTM will need to change ... profoundly.