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FDA accepts define.xml 2.0

The FDA (departments CDER, CBER, CDRH) recently announced to be accepting define.xml v.2.0. You can find the official announcement [here](#). Version 2.0 of the define.xml standard was published by CDISC in March earlier this year. Usually it takes some time for the FDA to implement (and be able to accept submissions using) a new standard, but this time it went very fast.

I guess this has to do with the fact that the CDISC team also delivered an excellent stylesheet for viewing the contents of the XML file. This stylesheet was developed by our team colleague Lex Jansen at SAS.

Moving from define.xml 1.0 to define.xml 2.0

As define.xml 2.0 is based on ODM 1.3 (define.xml was based on ODM 1.2), there are quite some changes. For example, “def:ComputationMethod” has been replaced by the ODM “MethodDef”. Also, the “WhereClause” mechanism has been added to allow to describe under which conditions a value list item is applied.

There are many advantages of using define.xml 2.0, but it might be that you or your systems are producing define.xml 1.0 files. So if you would like to submit using define.xml 2.0, you have a transition problem.

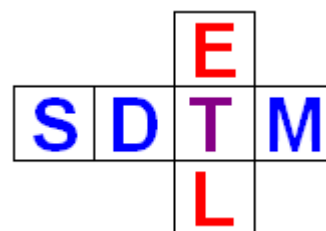
That is why we have developed an XSLT **stylesheet** that transforms define.xml 1.0 into define.xml 2.0 files, which makes it easier to develop and complete the define.xml 2.0 file.

Of course the result using the XSLT stylesheet is not a complete define.xml 2.0 file: you will for example still need to add the “WhereClause” elements and attributes, add the KeySequence attributes, and maybe also change some of the “descriptions”.

However, the stylesheet allows you to take a “jumpstart”. If you would like to obtain a copy of this XSLT stylesheet, just send a short mail to Jozef.Aerts@XML4Pharma, and I will be glad to send you a copy.

SDTM-ETL (TM) 3.0 in development

The rapid adaption of define.xml 2.0 by the FDA also triggered us to start with the development of the next generation of our popular SDTM-ETL™ software for generating and executing mappings between operational data (exports from popular



EDC systems) and submission data. So we are currently working very hard on a new major release which will be named “3.0”. This release will have an additional large number of very user-friendly features, and also full support for define.xml 2.0 (the user can choose between define.xml 1.0 and 2.0 at program startup).

Furthermore, version 3.0 will include all templates for the upcoming SDTM-IG 3.1.4 standard, which is expected to be released in the next few weeks.

Even more, SDTM-ETL 3.0 will have the possibility of generating SDTM files in the new SDS-XML file format, which was publicly announced during a CDISC webinar last week.

We expect to release SDTM-ETL 3.0 early 2014. So stay tuned!

The new SDS-XML standard

About 5 years ago, a number of volunteers within CDISC were developing a new format for transporting submission files as XML. The FDA by that time was starting a CDISC ODM pilot. A few months later however, the FDA unexpectedly discontinued the pilot with the argument that all future transport formats would have to be based on the HL7-v3 format. My opinion at that time (and it still is) is that HL7-v3 is completely unsuitable to transport SDTM/SEND and ADaM submission data.

In November last year, the FDA then held a public hearing asking for proposals for a replacement for SAS Transport 5 (XPT files). This triggered our development team to take up the work again, which now results in the publication (for public review) of the upcoming “Study Data Set XML” (SDS-XML) standard.

The new envisaged standard was publicly announced last week during a CDISC webinar, and I expect it to be published on the [CDISC website](#) in the next few days.

Tools for working with the new SDS-XML Standard

For the first time, the development team will also make a number of tools available to make a rapid adoption (especially at the FDA) possible.

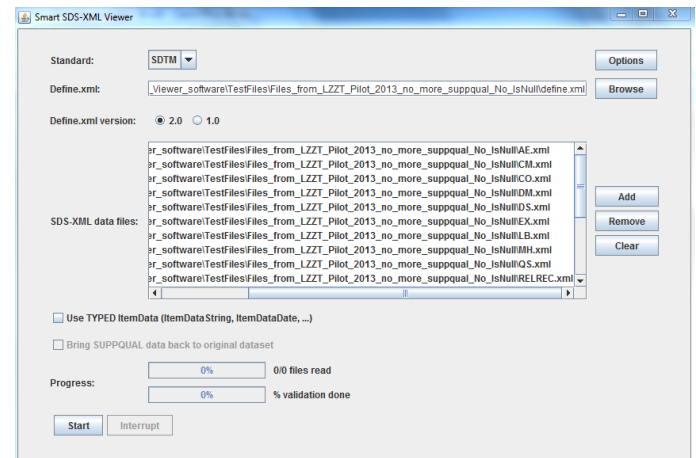
This will probably include scripts for import/export in statistical software, but also an open-source viewer software for inspecting submission data. This viewer is currently being developed by us. We baptized it the “Smart SDS-XML Viewer”

The “Smart SDS-XML Viewer”

The “Smart SDS-XML Viewer” is a replacement for the SASViewer, and will enable users to inspect submission files (SDTM, ADaM, SEND) in XML format.

The capabilities of the viewer however go far beyond of these of the SASViewer, as the “Smart SDS-XML Viewer” is “SDTM-savvy”, i.e. it understands what SDTM, ADaM and SEND are

about, and understands the rules and table relationships. The graphical interface is very similar to that of OpenCDISC, so that users that use OpenCDISC will quickly learn to work with the viewer.



The viewer also allows basic validation of SDS-XML data sets (against the SDTM rules and against the associated define.xml). It also understands the relationships between the tables, and e.g. allows to quickly inspect the DM table for any record in another data set by a single click. The same applies to quickly find the parent record from a SUPPQUAL, Comments or RELREC data set.

STUDYID	DO	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBSTRESN	LBSTRESU	LBORRES	LBORRES
CDISCPIL...	LB	01-701-1015	1	ALB	Albumin	CHEMISTRY	38	g/L	3.8	g/dL
CDISCPIL...	LB	01-701-1015	39	ALB	Albumin	CHEMISTRY	39	g/L	3.9	g/dL
CDISCPIL...	LB	01-701-1015	74	ALB	Albumin	CHEMISTRY	38	g/L	3.8	g/dL
CDISCPIL...	LB	01-701-1015	104	ALB	Albumin	CHEMISTRY	37	g/L	3.7	g/dL
CDISCPIL...	LB	01-701-1015	134	ALB	Albumin	CHEMISTRY	38	g/L	3.8	g/dL
CDISCPIL...	LB	01-701-1015	164	ALB	Albumin	CHEMISTRY	38	g/L	3.8	g/dL
CDISCPIL...	LB	01-701-1015	199	ALB	Albumin	CHEMISTRY	37	g/L	3.7	g/dL
CDISCPIL...	LB	01-701-1015	229	ALB	Albumin	CHEMISTRY	37	g/L	3.7	g/dL
CDISCPIL...	LB	01-701-1015	259	ALB	Albumin	CHEMISTRY	38	g/L	3.8	g/dL
CDISCPIL...	LB	01-701-1015	294	ALB	Albumin	CHEMISTRY	38	g/L	3.8	g/dL
CDISCPIL...	LB	01-701-1015	2	ALP	Alkaline Ph...	CHEMISTRY	34	U/L	34	U/L
CDISCPIL...	LB	01-701-1015	40	ALP	Alkaline Ph...	CHEMISTRY	50	U/L	50	U/L
CDISCPIL...	LB	01-701-1015	75	ALP	Alkaline Ph...	CHEMISTRY	41	U/L	41	U/L
CDISCPIL...	LB	01-701-1015	105	ALP	Alkaline Ph...	CHEMISTRY	43	U/L	43	U/L
CDISCPIL...	LB	01-701-1015	135	ALP	Alkaline Ph...	CHEMISTRY	47	U/L	47	U/L
CDISCPIL...	LB	01-701-1015	165	ALP	Alkaline Ph...	CHEMISTRY	53	U/L	53	U/L
CDISCPIL...	LB	01-701-1015	200	ALP	Alkaline Ph...	CHEMISTRY	41	U/L	41	U/L
CDISCPIL...	LB	01-701-1015	1	ALP	Alkaline Ph...	CHEMISTRY	45	U/L	45	U/L
CDISCPIL...	LB	01-701-1015	260	ALP	Alkaline Ph...	CHEMISTRY	46	U/L	46	U/L
CDISCPIL...	LB	01-701-1015	295	ALP	Alkaline Ph...	CHEMISTRY	44	U/L	44	U/L
CDISCPIL...	LB	01-701-1015	3	ALT	Alanine Am...	CHEMISTRY	27	U/L	27	U/L
CDISCPIL...	LB	01-701-1015	41	ALT	Alanine Am...	CHEMISTRY	41	U/L	41	U/L
CDISCPIL...	LB	01-701-1015	76	ALT	Alanine Am...	CHEMISTRY	18	U/L	18	U/L
CDISCPIL...	LB	01-701-1015	106	ALT	Alanine Am...	CHEMISTRY	26	U/L	26	U/L
CDISCPIL...	LB	01-701-1015	136	ALT	Alanine Am...	CHEMISTRY	22	U/L	22	U/L
CDISCPIL...	LB	01-701-1015	166	ALT	Alanine Am...	CHEMISTRY	27	U/L	27	U/L

We currently look for beta-testers for the viewer. The condition is that you want to invest some time in generating SDS-XML data sets from your own system, and then try them out using the “Smart SDS-XML Viewer”. Of course we can supply some test files, but it is important that the software is also tested with files from other systems and organizations.

As soon as the SDS-XML standard is published as “final”, the viewer will also be made available to the general public under an “open source” model.