

**Bimonthly newsletter of XML4Pharma,
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Lincoln Technologies acquired by Phase Forward

Lincoln Technologies, a major provider of IT services and products for clinical trials and submissions has been acquired by Phase Forward. The latter is well known as one of the two market leaders in clinical data management systems with their ClinTrial product. According to Phase Forward "Lincoln Technologies will be an engine for innovation for Phase Forward". Until now, Phase Forward has been unable to implement the CDISC standards in her product offerings, and this might be exactly the reason for the acquisition. If it is, ClinTrial customers may finally start to hope to obtain a CDMS that is CDISC compliant, with import and export facilities for CDISC ODM and Lab files. This would be a great breakthrough for CDISC: the implementation of the CDISC standards has for a long time been retarded by the refusal of the two major CDMS vendors to implement them. This however has also given many smaller, innovative vendors to come up with CDISC compliant systems, and conquer a non-negligible market share.

More information about the acquisition can be found at the websites of Lincoln Technologies and of Phase Forward.

Update of the CDISC ODM Checker soon available

We are currently working hard on an update of our CDISC ODM Checker. The ODM Checker is a software system for validating CDISC ODM files against the CDISC ODM standard version 1.1 or 1.2. The new version (0.6) will show a number of new features (like printing and export of the validation report to text or RTF files).

Furthermore, validation against the ODM 1.2 standard has further been enhanced. Also ODM files based on the newer ODM1.2.1 XML-Schema (allowing for vendor extensions) can now be checked, both against the ODM standard and the vendor extension itself.

The CDISC ODM Checker is available for free for CDISC member companies. Some of the companies that already use the CDISC ODM Checker are: Eli Lilly, DataTrak, the SAS Institute, Roche, Amgen, Sanofi-Aventis, Wyeth, Millenium.

An extension for validating define.xml files is in progress. It will be offered on commercial basis.

The new version of the software will be available before the end of September.

Improvements on the XML4Pharma Demo Application Server

A number of improvements have recently be implemented on our demo application server (www.XML4PharmaServer.com). This application server contains a good number of demo applications for use with the CDISC ODM and Lab standards. The recent improvements include improved handling of internationalized (i18n) CDISC ODM files (e.g. containing french or german characters), and improved automatic generation of e-CRFs (using XForms technology). The latter can be generated online, populated with data, submitted, and the result converted into CDISC ODM format.

Deutschsprachiger Kurs über CDISC ODM und define.xml

In Zusammenarbeit mit der Parexel Akademie in Berlin findet am Donnerstag, den siebzehnten November ein Kurs

namens "Die CDISC ODM und define.xml Datenstandards" statt. Folgende Themen werden behandelt:

- Einleitung CDISC
- Die CDISC Datenstandards / Konzepte
- Einleitung CDISC XML
- Anwendung des CDISC ODM Standards
- Der define.xml Datenstandard
- Beziehungen zwischen ODM, define.xml, CDISC SDTM und Lab Standards.

Weitere Information zum Kursinhalt und zur Anmeldung finden Sie unter www.parexel-akademie.de.

The CDISC ODM Viewer

Our CDISC ODM Viewer has drawn a lot of attention from users of the CDISC ODM standard. The ODM Viewer allows to view and navigate through a CDISC ODM file in a very user-friendly way and without any knowledge of XML. All data are transformed to neat HTML tables with HTML links provided in order to retrieve more information. Also, using the Viewer, subsets of clinical data can be retrieved and inspected. For example, one can easily retrieve all Pharmacokinetics collected data from subjects 1, 3 and 9 where the investigator was John Smith.

All necessary information, including screenshots, a movie on its use, and pricing information can be found at www.XML4Pharma.com/CDISC_Products/CDISC_ODMViewer.html.

Companies that would like to obtain a tailored version (tailored to the company needs) are invited to contact us. You will also find a screenshot at the end of this newsletter.

Oracle and XQuery

Oracle just released Release 2 of its Oracle 10g database. One of the new features is that it is now possible to use XQuery (the XML query language) to query as well relational as XML data in the database tables. Oracle had already introduced the

XMLType data type, allowing to store full XML documents in relational tables of the database.

The latest issue of Oracle Magazine (available online at www.Oracle.com/technology/oramag/oracle/05-sep/) has an article about how to build and execute XQuery queries in mixed relational / XML databases. Using XQuery to query relational data of course requires that the developer understands the XML view of relational tables.

CDISC US Interchange

For those that do really not know it yet: The CDISC US Interchange will take place on September 19-23 in Bethesda, MD. All necessary information can be found at www.CDISC.org.

News from the CDISC ODM Team

The CDISC ODM Team is now working hard on version 1.3 of the ODM standard. The standard will be 100% downwards compatible with the 1.2 standard, but contain a lot of new, exciting features. For example, it will be possible to define conditions under which study events, forms, item groups and items should not be executed or collected. New datatypes for Item Definitions like partialDate, durationDatetime, incompleteDatetime and many others will be provided. Better internationalization will be provided for labels in StudyEvent, Form, ItemGroup and Item definitions. It will now also be possible to group AuditRecords, Signatures and Annotations: the item to which the AuditRecord, Signature or Annotation belongs than just has a referencing attribute it. Especially SAS users and e-CRF vendors will take profit from the new features. The ODM team is currently discussing further new features.

Oracle makes JDeveloper IDE available for free

JDeveloper has been a rather popular Java IDE (i.e. development tool), until Eclipse (mostly developed by IBM) became available for free. As Eclipse is open

source, very soon, hundreds of plugins became available. Eclipse is now being used by over 60% of the Java developers community as their development tool. JDeveloper, the Oracle equivalent was previously priced at \$995, but now, Oracle has decided to make it available for free. Some of the functionality has however been taken out of the product: before, JDeveloper contained a license for the Oracle Application Development Framework (ADF). Also Borland, with his JBuilder IDE, has lowered its prices: the Foundation version even now comes for free.

Altova and XMLSpy heavily criticized

Market leader Altova (best known from its XMLSpy XML editor) has recently become heavily criticized. The attack comes from competitor StylusStudio, who published a report on non-conformity issues in Altova products. The criticism does not only concern XMLSpy, for being non-conformant to the W3C standards, but especially the by Altova newly released

XML processor (AltovaXML). The latter seems not to support the by developers highly beloved DOM (Document Object Model) and SAX (Simple API for XML Processing) processing interfaces. The Java and .Net interfaces seem to be just wrappers over C++ code, and the XQuery processor does not work against (XML) databases, but only against plain XML documents.

Also we had a number of difficulties with XMLSpy (see the CDISC discussion forum): In a previous (2005 SPI) release, XMLSpy was not able to interpret the ODM1-2-0 XML-schema correctly. Later, this was corrected, but the latest release (2005 rel.3) is still not able to correctly validate define.xml files or other ODM1-2-1 based vendor extensions.

The question whether the criticism of StylusStudio will bring them anything is doubtful: Stylus Studio XML editor comes at a price of \$995, whereas excellent XML editors are available on the market for less than \$100.

The screenshot shows the ODMViewer application interface. The main window is titled "Clinical Data Subsets" and contains several panes:

- Studies:** A table with columns "Studies" and "Metadata Versions". The "Studies" column contains "DEMO" and the "Metadata Versions" column contains "ORIGINAL".
- Subjects:** A table with columns "Subjects" and "Study Events". The "Subjects" column contains "1@1" and "2@1". The "Study Events" column contains "First Visit", "Second Visit", "Third Visit", "Final Visit", and "Adverse Events".
- Forms:** A list of forms including "Demography", "Social Use", "In- and Exclusion Criteria", "Concurrent Diseases", "Concurrent Medication", "Physical Examination Visit 1", "Vital Signs", "Hematology", "Biochemistry", and "Bacteriological Data".
- Item Groups:** A list of item groups including "Visit Date First Visit", "Identity", "Pregnancy Test", "Body", "Date Calc.", "Tobacco", "Cigarettes", "Alcohol", "Inclusion Criteria", and "Exclusion Criteria".

Below the main panes, there is a "Display Subset" button and a "Patient History" tree view. The "Patient History" tree view includes:

- Patient History
- Abnormals Specification
- Other Abnormals
- Study Drug
- Follow Up
- Patient Status
- End of Study
- Adverse Event Trigger
- Medication
- Concurrent Medication Rel. A
- Concurrent Medication AE No

At the bottom, there is an "Additional Functions" section with a "Clinical data subsets" button and a "Status: Done" indicator.

On the right side of the screenshot, there are three data tables:

Repeat Key	Transaction Type	Form	Repeat Date	Repeat	Check
yes	yes	yes	20050305	yes	YES
yes	yes	yes	20050308	yes	YES

Repeat Key	Transaction Type	Infusion Comment	Current Weight
Insert			88.0
Insert			56.0

Repeat Key	Transaction Type	Label 1	Label 2	Label 3
Insert		ASD--	ASD--443	ASD--443
Insert		TRZ--	TRZ--441	TRZ--441

Subject	Study Event	Form	Repeat Key	Transaction Type	Lab Selection	Date
1@1	First Visit	Hematology		Insert	LAB01	20050305
1@1	First Visit	Biochemistry		Insert	LAB01	20050308
2@1	First Visit	Hematology		Insert	LAB01	20050308
2@1	First Visit	Biochemistry		Insert	LAB01	20050308

Screenshot of the ODMViewer: the user can create subsets of clinical data and display them.