XML4Pharma develops CDISCLabChecker for Gereq

We recently developed a software system for Gereq, the Canadian Electronic Data Management provider. The software checks incoming CDISC Lab files (in XML format) against the Lab standard, and if any non-conformities are found, it displays these in a user-friendly way to the operator of the system. The nonconformity messages are also logged in order to comply to 21CFR Part 11.

This software has now been successfully integrated into the Gereq systems.

The CDISCLabChecker is also available to our other customers. As it is written in a modular way, it can easily be integrated in any server-based system. Of course it can also be adapted to the wishes of the customer. A version to check CDISC Lab files in ASCII format is also available.

Simplified versions of both versions (XML and ASCII) of the CDISCLabChecker are also available online on our application server at www.XML4PharmaServer.com.

The ODMViewer is back !

You remember the PHT CDISCViewer ? It was a very nice tool to visualize the contents of a CDISC ODM file, also allowing to create subsets of data and displaying these in a user-friendly, tabular way. Unfortunately, the PHT CDISCViewer was never adapted for the ODM 1.2.

Therefore, we developed a similar tool, the XML4Pharma ODMViewer, which allows to visualize as well ODM 1.1 as 1.2 files. Also the functionality has been extended.

As the tool has been developed in a very modular way, additional functionality can easily be added on request of individual customers. For example, functionality to sign an ODM document with an electronic signature (XML-Signature) and to verify a signed ODM document can easily be added on request.

More information about the ODMViewer is available at www.XML4Pharma.com/CDISC_Products/index.html.

XML4Pharma at the 2nd European CDISC Interchange in Paris

XML4Pharma will have a booth at the 2nd CDISC European Interchange, taking place from April 25-29 in Bussy Saint Georges (near Paris). During the exhibition, we will demonstrate the tools we have developed during the last two years.

At the conference, we will also give a lecture on a full overview of tools for working with the CDISC ODM and Lab standards (also from other vendors), and demonstrate a number of them.

If you would like to make a reservation for a discussion with us about specific topics, please let us know. This will also simplify our time planning.

Full information about the 2nd European CDISC Interchange is available at the CDISC website (www.CDISC.org).

News from CDISC: the new ODM extension mechanism

CDISC recently published a new ODM extension mechanism, allowing vendor extensions to be validated against a

separate XML-Schema. This new mechanism makes it possible to add extra elements and attributes (in their own namespace) to ODM elements, so that the ODM remains valid againts its schema, and so that the extra elements can be validated against their own XML-Schema

As this is an important step forward, especially for technology providers, we have immediately incorporated this in our training programs.

The new mechanism e.g. allows to add digital signatures (XML-Signature) to forms or itemgroups (until now only the full document could be signed) or e.g. to add digital information (ECGs, Xrays, etc.) to ODM files, as a vendor extension.

XML4Pharma is fully supporting this new extension mechanism, and will provide services to its customers to help them with the development of new vendor extensions and the necessary XML-Schemas.

A number of example files, from very simple to very complicated is also available from us upon request.

CDISC, eCRFs, XForms and PDAs

PDAs are becoming increasingly important in replacing paper in clinical trials. In combination with eCRFs, they allow fast, and reliable capture of data during clinical trial visits.
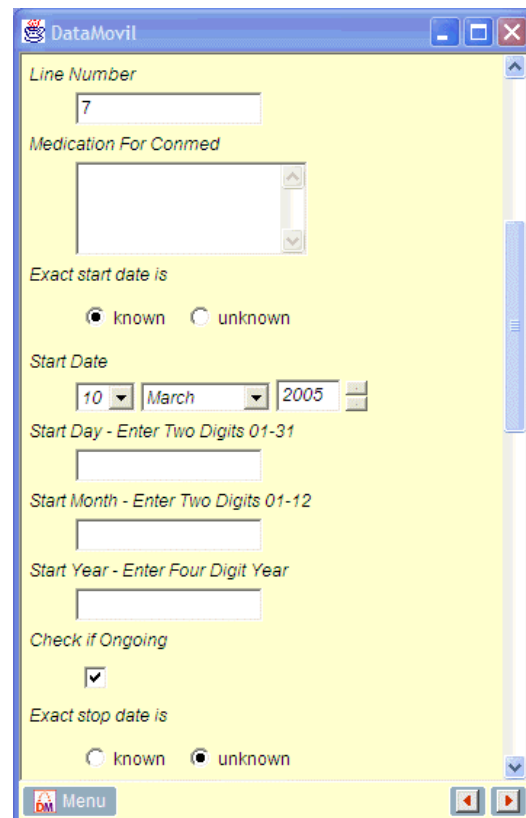
eCRFs can be designed so, that they are idiot proof, e.g. preventing that a character is given where an integer is expected, or that a date is entered that is non-existent (e.g. February 30th).

For developing such forms, several technologies are available. One of the younger, very promising is XForms, the new (open) standard for electronic forms from the W3C. One of the advantages of

XForms is that essentially the same form can be used in a web browser, a PDA or on a SmartPhone.

In the past, we already developed a method for automatic creation of eCRFs in XForms, and demonstrated how these can be used in a browser (this application is online available at www.XML4PharmaServer.com).

We now also recently demonstrated this for a PDA, using PDA software from Satec (DataMovil – www.DataMovil.info).

A PDA-eCRF (here in a PDA simulator) that was automatically created from a CDISC ODM file with a Study description.

The use of XForms as a standard for eCRFs will also be demonstrated at the CDISC Interchange in Paris.

Join us at the

2nd ANNUAL EUROPEAN INTERCHANGE
25-29 April 2005
Holiday Inn Bussy St. George
Paris, France

XML4Pharma is a

CDISC

Registered Solutions Provider