

Software tools for working with CDISC ODM, Lab, SDTM, and define.xml Standards

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ABSTRACT

The choice for XML as the basis of the CDISC standards made it possible to easily develop new software tools for working with these standards, as many libraries, parsers and frameworks for working with XML already exist. The presentation gives an overview of the IT-opportunities (enabling faster clinical trials with higher quality data) that have been made possible by the XML-based CDISC standards, such as automatic database creation, automatic generation of e-CRFs, web services for exchange of clinical data, etc.. An overview of tools for viewing CDISC files and for validating them against the standards is provided. The lecture includes a number of demos showing the power of the CDISC set of standards.

INTRODUCTION

Why do we need Information Technology (IT) in clinical trials ? Is it that we loose valuable time when distributing study definitions, collect clinical data and transform these into submission data ? If we only use paper, are our data of high enough quality ? Moving to the Information Technology age is now generally accepted as being necessary to perform clinical trials faster, with better data quality and at lower cost. However, software and its development is usually regarded as being expensive. If e.g. software needs to be developed for each study or set of studies that is being set up, its development costs will be huge.

If the whole industry however is using the same open standard for describing study setups, CRFs, administration data and collected clinical data, then technology vendors can much more easily develop standard tools, CDM Systems and software based on that open standard. Now, these open standards are there, and they are called CDISC.

Most of the CDISC standards have been implemented using the XML data format (itself being an open standard), with their respective XML-Schemas. The use of XML even more facilitates the development of software and information technology for use in clinical data capture, transformation and submission.

SOFTWARE TOOLS

The birth and further growth of the CDISC standards has created many new opportunities for technology vendors to come with new, innovative products, making it possible to perform clinical studies faster, with higher quality data and at considerable lower costs. Whereas the larger vendors have first been reluctant to implement the CDISC standards (giving new, small, creative vendors the opportunity to come up with innovative products), they have now recognized that their products and tools must become CDISC compliant in order not to loose their market share. Recent acquisitions and new product introductions exactly demonstrate this.

Smaller companies have already developed a good number of tools, including CDM Systems, based on, or for working with the CDISC set of standards. Examples of tools that have been developed so far include Checkers (for validating the content of CDISC files against the standard), Viewers, software for automatic creation of e-CRFs, software for adding electronic signatures to XML-based clinical data files, Web Services (for rapid exchange of clinical data over the internet), tools for setting up clinical studies, etc.. These tools are usually for working with the CDISC ODM and Lab standards (clinical data collection and management side). However, with the venue of the new define.xml standard, for the submission of metadata to the FDA, the tools development at the submission side has just started. So we may expect new tools based upon the CDISC submission standards very soon.

SOFTWARE DEVELOPMENT AND XML

Many of the CDISC standards are based on XML, with tendency increasing. As XML contains as well data as metadata (data about the data), XML files based on a standard (described in an XML-Schema) are essentially self-describing and can be easily validated against that standard. Many tools and especially software libraries for working

with XML already exist, so that developing software for working with XML based CDISC standards can be fast and relatively inexpensive. This is exactly the reason why smaller vendors have embraced XML and the CDISC standards very early. They can offer their products at a considerable lower cost than classic vendors, that have based their products on propriety data formats.

When developing its XML-based standards, the CDISC working groups have wisely decided not to reinvent new wheels. Where possible, they reuse already existing, well-established XML-based standards, such as XML-Signature and the standardized XML annotation for human languages (xml:lang). This means that it is very easy to couple existing technology based on these well-established standards to software tools for working with CDISC standards.

CDISC AND 21-CFR-11

From the start on, the CDISC standards have been developed with the 21 CFR Part 11 guidelines in mind. This means that, when the standard is correctly implemented, clinical data based on the CDISC standards, are 21 CFR Part 11 compliant. For software vendors, this means that when basing their products on the CDISC set of standards, 21 CFR Part 11 compliance comes largely for free.

CONCLUSION

The CDISC open standards enable to perform clinical studies faster, more reliable and at considerably lower costs. Software tools for working with the standards are rapidly emerging. At first, small innovative technology vendors have introduced a number of tools and CDM Systems for working with the CDISC set of standards. Recent acquisitions show that also the larger vendors are now forced to implement the CDISC standards rapidly. With the venue of the define.xml standard, also tools and software for submitting information in CDISC format to the regulatory authorities are expected to emerge very soon.

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