



Formedix: Clinical Trial Efficiency Using CDISC Standards

Formedix develops clinical trial automation software and services to promote efficiency for CROs, Pharmaceutical and Biotech companies, and EDC vendors. Formedix has been involved in using CDISC standards for over 10 years, and their Technical Standards Director (who has won 2 awards with CDISC) is currently working heavily on CDISC's Define.xml. CDISC standards have been integral in ensuring that Formedix's clients see large-scale reuse, and substantial reductions in resources, set-up and EDC build time. In this article, Formedix proves that you can automate clinical trials anywhere using the CDISC standards.

Saving Time and Money

Using CDISC standards is all about making the clinical trial process more efficient, saving time and money. Through the content libraries that Formedix has established for many of its clients, from small biotechs to large multinational firms, they have found that there is significant content reuse, as much as 70-80% reuse in some cases, with 20% less maintenance cost. These content libraries span the entire clinical trial process end-to-end, and have been found to have a quick ROI, in one case in as little as eight months.

In the Study Set-Up stage, specification auto-generation, whether it be through annotated CRFs, eCRFs, tabular data specs, track changes, validation specs and more, can all be automated using CDISC standards, and can be presented in commonplace formats like MS Word, Excel, PDF or even the actual eCRF document viewed in HTML. CDISC standards ensure specification data gathered during the Study Set-Up stage is annotated, viewable, and is a vendor-neutral way to produce specifications. Clinicians, data managers, and biostatisticians can all benefit from this auto-generation. Even more, Formedix's clients appreciated the ability to keep their old Excel formats and auto-generate and use the content. One Formedix client found that there was a 68% reduction in study set-up time.

In the Study Build stage, Formedix has automated the EDC build, leading to a median reduction of 55% in EDC build time, with an expected reduction of 80% by the end of the year. Mark Wheeldon, CEO of Formedix stated, "If you have great integration, you will find that the Study Set-Up and Study Build stages can almost merge. If you use CDISC standards, you can build out a lot of the EDC. You approve a specification, you hit a button, and you build out most of the EDC."

In Study Conduct and Analysis, Formedix found that using CDISC ODM was a great way to drive dataset production, and realized a 76% reduction in production time. In the Study

Conduct and Analysis stage, you can verify if the dataset is SDTM compliant, if the data matches the original specification, if your form looks like the metadata established at the beginning of the process, and if it has been implemented correctly. You can also check if the dataset matches the library content, or if someone deviated from the standard, and determine the net effect of that deviation. All of this can be done to automate some of the validation process. This shows true automation across the end-to-end clinical trial process, all by using a framework that has been provided by CDISC.

Creating Perfect Libraries

It used to be that inside the traditional data management system, reuse of data would be around 85% for certain standard elements after 25 studies; and after 150 studies this would finally reach 95%. CDISC offers not only reuse from the start, but across the entire clinical trial process, and a model to store this in a vendor-neutral fashion. Mr. Wheeldon emphasized, “Why I think CDISC is perfect, is that you can build in quality up front. You can use tools with CDISC to see what’s actually changed. What do I need to test and validate more extensively? What has changed on my form? On my dataset? They’re vendor-neutral and portable, they can be reused across a whole trial across multiple platforms, i.e. EDC, ePRO, and multiple vendors.”

An example of this can be found through a client of Formedix, which had all of their data stored in MS Word, Oracle, Excel and PDF, and while well curated, could not be executed in a machine-readable format. Formedix successfully converted the content. Now this client has a massive reusable library, and has already shown a large savings in resources in the management of that library, expecting further resource savings down the road. Eli Lilly kindly made their CDISC ODM library available to the public for download.¹

Enabling the Perfect Study Set-Up

It used to be that multiple people would generate multiple kinds of specifications in a linear fashion. Now using CDISC standards, you can drag content from your metastore, which you can use to generate multiple, machine-readable types of specifications, which are easy, understandable, and can be shared internally and with CROs, all automated from a single CDISC-based metastore. As one example, information from your metastore can be used to generate an ODM document, which can then be used to auto-generate CRFs, eCRFs, DB aCRFs and SDTM aCRFs. One piece of metadata can auto-generate visualizations from multiple systems.

Study Build Automation

To build a study, you take content from the metastore, auto-generating many of the specifications, then generating the files required to build EDC/ePRO to Perceptive Informatics DataLabs EDC, Nextrials Prism or Medidata Rave, all directly from CDISC using the Core CDISC model as well as some extensions. You can extend this further to build out to other systems as well. Downstream, you can test what you finally ended up building versus what you intended to build. Formedix notes that while the creation of libraries is

¹ <http://lillyodmlibrary.codeplex.com>.

excellent and study set-up is well automated, with study build, integrations need to be made tighter, and with study conduct and analysis, there is further work to be done to make this stage more efficient as well.

Wheeldon pressed that there is a myth that you cannot do calculations and complex edit checks with CDISC ODM and move these to EDC systems. This is untrue, and as Wheeldon stated, “we need to raise the integration bar. You can get methods, conditions and formal expressions into any of these EDC systems by extending the constructs and parameters that CDISC has provided us.” Formedix has found that it is possible to get 80% automation of complex edit checks. They expect to be able to automate between 80-90% of the entire EDC build by the end of the year, meaning that it will be possible to get complex and universal edit checks across an EDC system, within multiple areas where validation is run. Formedix noted the partnerships that they have in place to ensure tight integration at present. The company is working with several partners to develop even more of these integrators in 2013.

Optimizing Study Conduct

Optimizing study conduct is all about being able to stream data from end-to-end. To do this, you extract data from an EDC system in ODM, and this ODM should match the design that was created in the beginning. This should enable automation from ODM to SDTM, but this is not usually the case. In reality, most ODM that comes out of an EDC system doesn't match the metadata that comes in, forcing companies like Formedix to rely on proprietary dataset formats. This, in turn, requires the management of multiple types of proprietary EDC formats in libraries. This isn't ideal, and the generic structure, ODM, provided by CDISC would be better. Utilizing ODM allows data to stream across the clinical trial process, enabling a true, highly scalable end-to-end process.

To learn more about the work Formedix is doing to enable clinical trial automation, please visit their website: <http://www.formedix.com>. To view the slides from which this article was developed, please visit their download page: <http://www.formedix.com/downloads/>.

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