

> Setting the Standard:  
Merge eClinicals' Use of the  
CDISC Format for Integrating  
Data in Clinical Trials

**+** *Online Electronic Data Capture (EDC) systems have very real and measurable benefits. Immediate feedback on the quality of data through the use of in-system edit checks means that investigators can correct errors or explain anomalies while the patient record is still at hand.*

*Monitors have real-time access to data from any location, thus reducing the expense and hassle of unnecessary site visits. There are many other benefits to EDC but the majority of clinical trials are still performed using pen and paper. Why? Part of the reason for the slow adoption rate stems from the impact of EDC on existing processes EDC brings with it change and change can be unsettling, especially to an organization with an established and well-tuned clinical trial process.*

### **Merge eClinical's EDC supports the integration of multiple data sources from other systems**

Although this process change can be difficult, companies engaged in clinical research have smart employees who are well able to see the benefits of EDC and who are willing to make the necessary adjustments to maximize its potential.

But if the people are flexible, the existing computer systems normally aren't. How will your new EDC system work with your Clinical Data Management System (CDMS) or with your eSubmissions system?

The typical clinical trial is reliant on a number of computer systems. These systems may be internally developed or vendor supplied. Making these systems talk to each other—in such a way that Serious Adverse Event (SAE) data can be reconciled between your CDMS and your SAE Reporting system—can be a major project for your IT group. It can also be a significant expense if you outsource that work to consultants. For these reasons, any project that introduces new technology into the clinical trial process normally includes a thorough review of its compatibility with the existing systems.

Adopting technologies that are designed to work with existing systems will always be more attractive than those that require new interfaces. So, if you have a CDMS system from a vendor, it is natural to take a long hard look at that vendor's EDC system with the expectation that it integrates well right out of the box. You might not be getting the best EDC system possible, but maybe you will get the best system for your existing environment.

### **The mission of CDISC is to lead the development of global, vendor-neutral, platform independent standards to improve data quality and accelerate product development in our industry**

This situation, in which sponsors are chained to vendors

and systems they don't really want, is a challenge for pharmaceutical and biotech companies. It limits choice and ultimately affects the flexibility and competitiveness of the organization. Ideally, you would be able to move data between your CDMS and your EDC system with ease; you should be able to extract data from CDMS system A and import it into CDMS system B without creating custom import and export processes. In short there should be a standard data interchange between systems dealing with clinical data.

### **A Common Standard**

As many data managers know, there is a set of standards-based data models designed specifically for clinical research: the Clinical Data Standards Interchange Consortium (CDISC). The CDISC standard is, simply stated, data formats that allow vendors and sponsors to share information without having to translate it first.

The CDISC mission is: "to be an open, multidisciplinary, non-profit organization committed to the development of industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development."

CDISC is working on the standards to make the movement of data between clinical data systems as easy as possible. Systems will always have some differences but CDISC aims to create a set of standards for the core information that is the same between systems while allowing for extensions to the standard where systems differ.

### **The CDISC Operational Data Model is a specific recommendation for the universal formatting of clinical trial data**

Most of the CDISC standards use text-based extensible

markup language (XML). XML is a good choice for this purpose because the ability to read and process an XML document is built into most programming languages, while still being understandable to those who can read and understand the code. This makes it relatively easy to build systems that read and write data to the CDISC XML standards.

## Merge eClinical and CDISC

CDISC is working to create standards in a number of areas: Data submission standards, standards for laboratory data and standards for analysis datasets; but as an EDC vendor, Merge eClinical is most interested in the Operational Data Model (ODM) standard. The ODM defines a standard for the representation of studies and study data. This is the type of data that CDMS and EDC systems deal with everyday.

For instance, the ODM shows how questions are related to pages and to visits within the study and provides a way to encode the collected data in a system-neutral way. This system-neutrality is the key to solving the vendor lock-in problem. It means a CDMS or EDC system that is set up to consume data in ODM format does not need to know where that data came from. In the same way, a system that produces data in ODM format does not need to know who or what will eventually read it.

### **Sponsor support for the CDISC ODM standard will drive vendor progress**

The ODM is a kind of lingua-franca for clinical data systems, a universal translator for study designs and data. But it is no panacea.

The ODM provides the language, but we still have to make our clinical data systems talk to each other. With the CDISC standard, we only have to support one interface so; instead of asking, "Does system A talk with system B and in my organization?" we can simply ask "Does this system talk using the ODM?" When the answer is "Yes" we get the ability to use the best CDMS with the best EDC system in a truly integrated manner no matter whom the vendors are. We get to choose the best tool for the task at hand. All of which is impossible without vendor support.

The good news is that many of the major vendors are already CDISC members and are actively engaged in implementing and improving the standard (see links section for a link to the full list of members). Progress on implementing the ODM standard is normally showcased each year at the DIA annual convention.

## What Merge eClinical is Doing

Merge eClinical is part of the drive to make ODM a standard for clinical data interchange. As a data collection company and a member of CDISC, our goal is to improve the speed and quality of the data collection process in order to provide the data to the client for analysis as quickly as possible.

### **Data access and availability is the key to increasing adoption of eClinical technologies**

Merge eClinical has a system for generating ODM formatted data from our data-entry database. The system comes in two flavors: a Windows application and a web page from which you make your requests. Both flavors allow a user to connect to an Merge Healthcare Web Service that provides the data over a secure connection. The system allows the user to select individual patient records or the data for an entire site. The returned ODM data can be displayed in its native XML format or saved for further processing by some other ODM compliant system.

## CDISC Export as a Web Service

The ability to obtain ODM data from the Merge eClinical database is very useful, but what if you need to get this data on a daily basis in order to feed it into your CDMS? One approach is to go to the ODM Request application each day, select the patients to be exported and make the request. Undertaking this task with accuracy 365 days a year would be very time-consuming, not to mention boring for the person responsible.

To solve this problem Merge eClinical has developed its ODM Request system as a Web Service. This allows an automated system to be set up which makes the request automatically, everyday, without human intervention. Of course, this requires that you employ a programmer to create the request system but the web-service makes this simple in most programming languages (Java, C++, Visual Basic, .NET).

This type of automated integration is an important step in breaking down the barriers between clinical trial systems. The ODM makes transferring data between these systems easier. Automated processes and open interfaces like Web Services provide the infrastructure to ensure that the data moves between the systems on a scheduled or on-demand basis.

## The Future of Data Standards

CDISC standards will become an increasingly important part of the clinical trial system landscape. When systems are able to communicate without custom bridges, organizations will be able to select the best system for their needs. Vendor lock-in will become entirely voluntary, based on the merit of the solution and not on fear of incompatibility.

Of course, not all vendors are pleased with the idea of increased customer choice and one large vendor has already cancelled its ODM interface. To a large extent the benefits of integration through standardization will only be achieved when organizations demand that their vendors comply with the standards.

## About Merge Healthcare

Merge Healthcare is the leading provider of enterprise imaging and interoperability solutions. Merge solutions facilitate the sharing of images to create a more effective and efficient electronic healthcare experience for patients and physicians. Merge provides enterprise imaging solutions for radiology, cardiology and orthopaedics; a suite of products for clinical trials; software for financial and pre-surgical management, and applications that fuel the largest modality vendors in the world. Merge's products have been used by healthcare providers, vendors and researchers worldwide to improve patient care for more than 20 years. Additional information can be found at [www.merge.com](http://www.merge.com).

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