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Will CDISC Demo Drive Demand for EDC/EHR Integration?

By Deborah Borfitz

Four major pharmaceutical companies and a California systems integration services firm are providing the "brain and brawn" -- as well as the funding – to demonstrate the feasibility of integrating data capture needs of clinical research and disease prevention with electronic health records (EHRs), says Tanyss Mason, director of communications for the Clinical Data Interchange Standards Consortium (CDISC). At present, "it's not unusual for [investigative] sites to have an EHR as well as multiple EDC [electronic data capture] tools, and it's unwieldy."

CDISC, which is spearheading the demonstration project, views data capture as a "single-source encounter between an investigator/physician and subject/patient," says Landen Bain, CDISC liaison to healthcare. The "key idea" is to have a data-capture form appear on the computer screen in an EHR session. "If you have an EHR, it's contorted to go to a different computer and a different application to enter data for a clinical trial when the data originates inside the EHR and that's where you do [most of] your work."

The collaborative project has five different "scenarios," each representing a different aspect of connectivity, says Mason. The clinical trial execution scenario uses Cerner's EHR to fill out and return a case report form retrieved from Lilly. The scenario for disease or patient registries involves an Allscripts user working in a similar fashion with a data-capture form from Outcome, the EDC agent for Genzyme.

The bio-surveillance scenario, sponsored by San Diego-based Science Applications International Corporation (SAIC), has an Allscripts user fill out an onscreen form about a disease outbreak and send it to the Centers for Disease Control and Prevention. The user is prompted by "flags and triggers identified during the data entry process," says Mason.

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The post-marketing safety surveillance scenario likewise uses Allscripts' EHR, but as the means to fetch a form from Pfizer to report a suspected adverse event, continues Mason. The scenario for clinical trial laboratory data has a Siemens' EHR user receiving and completing a form from Novartis for requested lab tests (and possibly radiology images).

The common theme, says Bain, is an easy-to-use "integration profile" called Retrieve Form for Data-capture (RFD) that was co-developed by CDISC and Integrating the Healthcare Enterprise (IHE), a healthcare interoperability enabler. "The EHR is the retriever." The RFD creates a "scenario for connectivity that in the real world makes sense to real people." It's a bit like a "cookbook" that provides a different mix of standards for different data collection occasions, such as clinical research or public safety.

Different versions of the RFD, created for each of the five scenarios, can be seen in action at CDISC's "New Directions" life sciences demonstration of the HIMSS (Health Information Management Systems Society) Interoperability Showcase. The showcase is part of the annual HIMSS conference and trade show February 25 to March 1 in New Orleans. The dress rehearsal takes place a month earlier at a Connectathon in Chicago, which Bain describes as "a giant geek fest for techies."

If all goes well, CDISC plans to take its show on the road, possibly to the annual Drug Information Association meeting and CDISC interchange meetings in the U.S. and abroad, says Mason.

Real-world integration will occur once investigative sites, as customers of EHR, start to specifically request an interface for clinical trial data capture as a system feature, says Bain. Those customers will be among the 20,000-30,000 people expected to attend the upcoming HIMSS conference. "There's a lot of latent market demand [for integration] out there."

The other possibility is that pharmaceutical companies will push EDC vendors to make their data-capture forms compliant with CDISC's ODM (Operational Data Model) standard and available for use with a technology called Xforms, as Outcome has done. That's what makes it possible for the EHR to respond to requests for research-related forms, says Bain.

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Clinipace: Front Runner on Integration

By Deborah Borfitz

Integration of sponsored disease/patient registries with electronic health records (EHRs) will happen sooner rather than later, according to Jeff Williams, CEO of Clinipace, a clinical research software company based in Research Triangle Park, N.C.

Clinipace expects to develop such interfaces for two of its clients over the coming 12-18 months. Interest is being driven by the "desire to eliminate dual data entry for data common to a clinical trial or registry and an electronic medical record system," says Williams, previously senior executive for an EHR company.

The major challenge is creating a way for clinicians participating in a registry to collect a specific data set without having to enter the same information twice -- regardless whether they're using Cerner, Epic, Allscripts, or some other EHR system. The plan is for Tempo, Clinipace's Web-based registry and clinical research platform, to collect registry data as well as extract certain data from the EHR, says Williams.

The best long-term solution requires the interest and cooperation of multiple EHR vendors who until recently haven't felt sufficiently compelled to partner with their counterparts in the research world. Williams sees the ideal solution as a "widely accepted standard, not one-off custom interfaces for each EHR." He says he's hopeful that real traction in this area will increase after February's HIMSS conference, when CDISC debuts an integration profile that can be used to link clinical trial data-capture to any EHR (see "CDISC Demo" story, above).

Standards, while holding substantial promise, are "the big question mark," says Chris Porter, vice president of

operations and business development at Clinipace. "They are still evolving, and CDISC is relatively new."

The timetable on integration of the registries is "sponsor-dependent," says Porter. Big pharmaceutical firms, which sponsor large-scale registries, will probably have to pick up the tab for these types of initiatives to proliferate. They certainly could benefit from the investment. "For 10 years, they've sought to harness the clinical potential that EHRs hold in shortening the clinical development timeline and it's still...just out of reach." As a means of identifying sites and subjects for trials, EHRs promise to be a huge cost saver. But they "aren't designed to collect data in a way consistent with research-driven protocols and clinical research workflow, and therefore the EDC [electronic data capture] integration is necessary."

Williams' view is that "all clinical research," not just Phase IV studies, will drive integration "since earlier phase research is being conducted today in environments [such as hospitals and academic medical centers] where EHRs largely exist and the integration is missing." Widespread integration will happen first with disease/patient registries to develop observational databases. "EDC integration for controlled clinical trials and Phase IV studies will come along on the heels of registries as benefactors of the registry integration."

Integration between clinical trial and patient record systems is not an entirely new idea. For a decade now, Holston Medical Group (HMG) -- a relatively small, non-academic healthcare organization in Kingsport, TN -- has used Allscripts' TouchWorks EHR to enroll thousands of patients in more than 250 clinical trials. TouchWorks identifies patient candidates via computer analysis of discrete data points, assesses their eligibility for a trial, and alerts physicians at each of HMG's 26 clinics to a patient's involvement in trials so there are fewer protocol violations and faster reporting of adverse events, according to a white paper by Allscripts. Income from clinical research at HMG skyrocketed from $110,000 in 1996 to about $3 million this year.

TouchWorks is interfaced with Study Manager, the most widely deployed clinical trial management software, according to Allscripts spokesperson Todd Stein. Study Manager was developed by Seattle-based Advanced Clinical Software, with whom Allscripts strategically partnered earlier this year.

DSG Launches Data Management Division

By Ann Neuer

With adoption of electronic data capture (EDC) trending upward at a healthy clip, provider DSG Inc. is riding the wave by offering clinical data management services to its EDC customers through a newly created Data Management Division. Launched in mid-2006, the division provides an array of services such as design and review of electronic case report forms, data encoding, and ongoing review of data and logic checks.

These are services that many sponsors typically outsource to clinical research organizations (CROs) but, if DSG has any say in the matter, not for long. As Tina Varallo, Vice President Clinical Data Management explains, the new division opens opportunities for streamlining the study start-up process.

First among them may be eliminating the need for sponsors to contract with CROs for data management functions. "With the expertise we have in-house, DSG can work directly with sponsors to handle the many details surrounding study start-up for trials using our eCaseLink EDC technology," says Varallo. This would cut out lengthy kick-off meetings with the vendor, the sponsor, and the data managers from the CRO, in which best practices and processes for EDC-based studies are laboriously hammered out, followed by continued contact with the CRO throughout the trial, Varallo says. DSG can essentially take over this function, managing all aspects of the data setup and cleaning processes, delivering clean, reportable datasets in CDISC format to the sponsor in a more timely and cost-efficient manner.

The opportunities don't stop there. Smaller players, such as biotech companies, may be eager to conduct EDC-based trials but sometimes lack a data management department to perform the necessary study setup and handling of the resulting clinical data. Varallo explains that these clients are good candidates for the one-stop-shopping approach offered by DSG. "A small biotech without a data management department is relying on someone else to set up all of the screens and edits, and review and clean all of their data. DSG can now provide those services along with our EDC tool," she says.

According to Tony Varano, president and CEO, the company has long been performing many data management functions. By formalizing these efforts into a division, the company is better positioned to work directly with the sponsors' data management teams interested in deploying EDC initiatives. "An EDC environment is very proactive compared to a paper-based environment, which is where many sponsors have most of their expertise and processes in place to support those

types of studies," he says. "It is our objective to work with sponsors to facilitate the kinds of process changes needed to make data management more efficient"

The services offered by the Data Management Division are being well accepted as evidenced by the level of interest and the number of contracts signed for this service in the short six months since its introduction, says Varano. "Now, we are typically being asked to propose our data management services when we bid our EDC technology. Also, some of our existing EDC customers are looking at the service."

Ann Neuer is a freelance writer based in Cincinnati, Ohio. Through her company, Medical deScriptions, she writes extensively in the clinical trials, pharmaceuticals, and biotech sectors for publications such as *CenterWatch, The Monitor,* and *Applied Clinical Trials.* She is co-author of *How to Grow Your Investigative Site,* a book published by Thomson CenterWatch intended to help investigators build the infrastructure they need to perform successful clinical trials.