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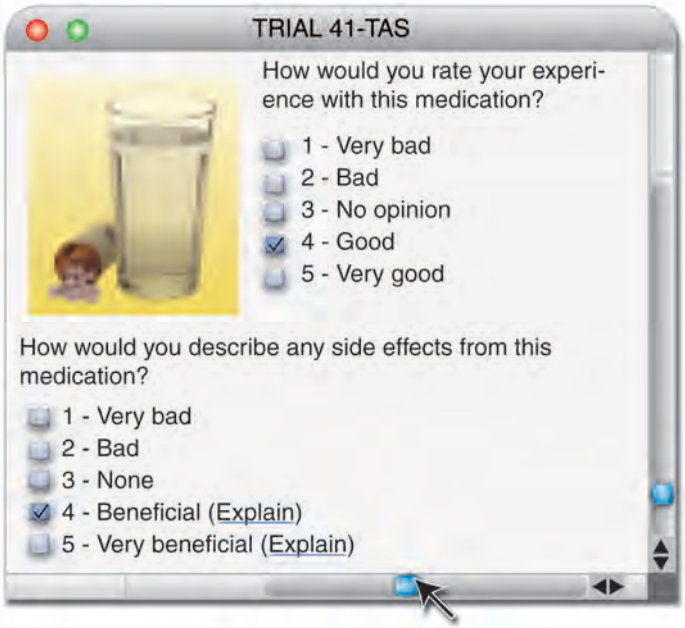
A Web application reaches out to data and researchers.



CONNECTING FOR CLINICAL TRIALS

By Zack Martin, Managing Editor

CLINICAL TRIALS AND PAPER SEEMINGLY go together like peanut butter and jelly. But some provider organizations are moving much of their trial work to the Internet using Web-based applications that enable them to collect trial information and collaborate more efficiently with research partners.

In addition, a growing trend among providers involved in clinical trials is to rely on other information systems—notably electronic health records—to feed patient information to clinical trials applications to ensure researchers don't have to search far and wide for data.

The University of New Mexico Health Science Center and the University of Michigan Health System, for example, both use clinical research software from Fremont, Calif.-based Velos Inc. to provide clinical trial researchers with a customizable system to collect data and track the status of various trials.

The systems are designed to support clinical trial functions such as patient recruitment, scheduling, project planning, protocol compliance and milestone management, among others. But neither facility is using the software in a standalone fashion. While their strategies differ, the delivery systems are pushing to interconnect the software with various clinical systems via Health Level Seven interfaces.

Their efforts exemplify the reasons why there's not a lot activity in the standalone clinical trials software market, says Bruce Ekert, senior manager at Boston-based Beacon Partners Inc.

"Most of the data needed to manage a clinical trial is in an EHR system, so organizations are not showing much interest in trials software that runs on its own," he says. Some EHR applications, such as software from Chicago-based Allscripts LLC, initially were developed for the clinical trials market and eventually expanded to encompass the entire medical record.

"If an organization is looking for software to conduct a clinical trial they most likely will find what they need in an EHR," he notes.

At the Department of Radiation Oncology at the University of Michigan Health System, Ann Arbor, the Velos clinical trial software has evolved into a departmental EHR, says Julie Wietzke, former clinical research manager for the department. Wietzke, who worked in the department when the system was implemented about 18 months ago, has taken another position within the delivery system.

"We wanted a flexible application that would enable us to capture patient information, whether or not that patient was involved in a clinical trial," Wietzke says. "We use the software to compile data—such as diagnosis, consultations and treatment course—on every patient we treat." In addition, the software is linked to some of the delivery system's enterprise clinical applications so it can collect additional treatment information, such as if a patient is hospitalized or has any lab tests performed.

But the chief reason the University of Michigan installed the software was to replace an aging, homegrown database used to manage clinical trials, Wietzke adds.

To customize the database for clinical trials, such as adding a table or data field, the department needed to bring in a programmer, and the work would take weeks or even months to do, she says.

Easy modifications

Now, clinical trial coordinators can do such customization themselves using Web-based tools, and a programmer is required only to do the "heavy lifting," Wietzke says. "What used to take weeks or months now takes hours."

The ease of using the Web-based software also has enabled the department to expand the number of users who are authorized to "touch" the software. Because of the difficulty of interacting with the old system, researchers

and others involved with trials sent all information to a central coordinator, who would manually enter information into the database.

Other authorized users at the delivery system's eight oncology radiation clinics now can enter and access clinical trials data. This leads to more accurate information in the system because it's not being passed among multiple people, Wietzke says.

The application also can be used to locate archived hard copies of patient information. A notes function enables researchers to tag a patient file with the location of archived forms.

In 2004, when the University of New Mexico Health Science Center was looking for software to automate its clinical trials for cancer research, it initially focused on finding an EHR to handle the task. But nothing on the market had the flexibility the university needed, says Claire Verschraegen, M.D., a professor and clinical study investigator at the delivery system. The administration of clinical trials requires a great deal of ongoing electronic forms and data field design work, which Verschraegen felt was not feasible to do with EHR architectures.

The clinical trial information system is anchored by a database that is used to store all the data on a clinical trial and make that information available not only to researchers at the University of New Mexico Health Cancer Research and Treatment Center, but also to a network of investigators and facilities they partner with for studies.

One of the most important efficiency gains has been forms automation. When clinicians relied on paper, they often had difficulty finding the most up-to-date protocol and consent forms, especially when the clinical trial spanned across different facilities.

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The Web-based system enables any clinician to download the proper consent forms and get patients enrolled in trials. At the University of New Mexico, the software has been linked with an EHR system, from Kansas City, Mo.-based Cerner Corp. When a patient at the facility is enrolled in a clinical trial, their demographic information is sent to the clinical trials software.

However, the same type of interface is not yet available for clinical data housed in the EHR, which means that researchers must switch back between the EHR and clinical trials software. This has been a sore point with researchers, Verschraegen says, but the cancer center does not have the resources at this time to build those interfaces. I.T. staff, however, is working on interfacing the clinical trials software with the laboratory information system to get results sent directly into patients' files in the clinical trials system.

A big payoff of the clinical trials software has been its ability to keep patient records up-to-date and enable researchers to share information quickly, Verschraegen says. The facility has set up the system to be a central exchange for clinical trials it manages. Clinicians at the facility, as well as partners at other facilities, can view the information, but only a group of data coordinators and research nurses can add information into the system.

In addition to providing tools for its network of researchers, the University of New Mexico also can communicate much more efficiently with the National Cancer Institute and regulatory agencies, Verschraegen says. •

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