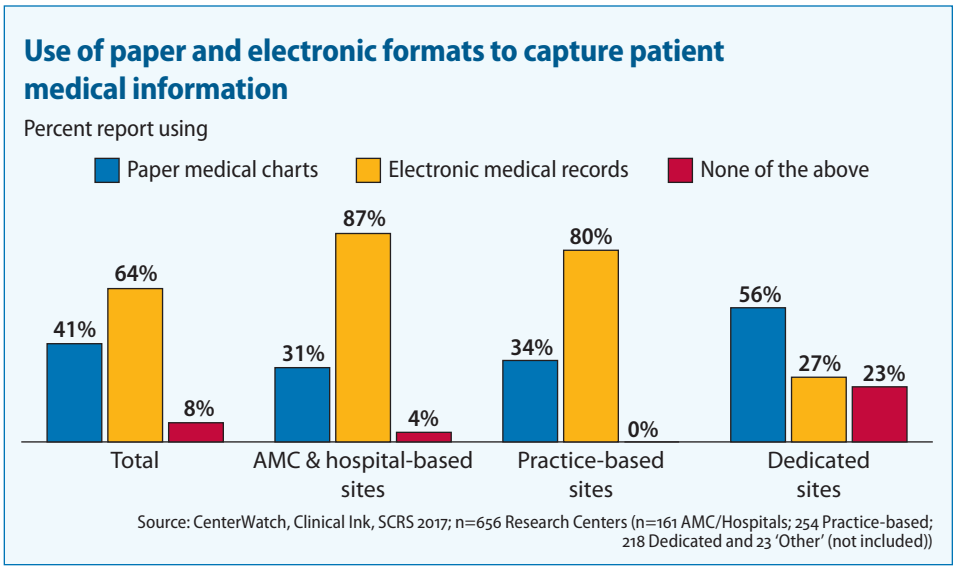
The CenterWatch Monthly

February 2017 A CenterWatch Feature Article Reprint Volume 24, Issue 02

The need for—and barriers to—adopting eSource

New regulation and partnership may finally end poor interoperability and the aversion to change

By John W Mitchell



Electronic data collection responsibility borne by investigative sites to support each clinical trial is onerous, with little to no relief in sight. In many instances, these responsibilities are being managed at the same time that paper data collection processes are prevalent.

Sites are inputting medical and medication information into electronic medical records (EMR), data into electronic data collection (EDC) systems, and site personnel are creating and completing study-specific source data document templates to capture case report form (CRF) and site activity and management data.

According to a new 2017 CenterWatch study, conducted in partnership with Clinical Ink and the Society for Clinical Research Sites (SCRS), investigative site staff are juggling the use of disparate systems and they are spending an inordinate amount of time—an average of 19 hours per study—creating source document templates typically in Microsoft Word, Excel or PDF format. The survey, conducted online in late 2016 among 656 investigative sites, shows that investigative sites want a single eSource solution, but that the integration of EMR and eClinical data is making very slow progress.

Doug Pierce, president of Clinical Ink, sees the lack of interoperability as a primary barrier. "The survey findings clearly show that the majority of sites are using three systems: an EMR system, paper source documents and an EDC application."

Pierce told CenterWatch that data are entered using a variety of disparate systems, and the study sponsor and their CRO must monitor that data. "Contrary to what one often hears, the widespread use of EMRs to capture patient medical information has not eliminated the need for systems designed to capture specific, protocol-required information," said Pierce.

The vast majority (79%) of investigative sites report in the CenterWatch survey that recording study-specific data electronically instead of re-entering data into a separate system would save time and improve accuracy. This would only work if such a system was not cumbersome (i.e. did not lengthen the study time), was user-friendly and didn't take away from time with patients.

Nearly half of survey respondents report that the reason for these inefficiencies was due to lack of a standard format for collecting and transferring data. Academic sites were most likely to report site policy restrictions and lack of IT support as complicating factors.

"The value of standards is that one can 'plug and play' with platforms and tools and use what they like, while still being able to support interoperability between systems, to exchange data in a meaningful way between all sorts of different tools," said Rebecca Kush, Ph.D., founder, president and CEO of the Clinical Data Interchange Standards Consortium (CDISC). "This actually encourages innovation and progress."

Almost two-thirds (64%) of sites report using EMRs to store patient medical information. Of those sites that use both EMRs and paper, only about 60% of the records are electronic. Half of investigative sites report that they must make duplicate entries and almost all investigative sites (92%) report discrepancies between information in a patient's medical chart versus that found in patient reports.

John Manns, senior director, Clinical Innovation at PPD, said, "Sites are moving away from paper, but we still see a lot of efforts that sites have to make entering duplicate data into multiple systems."

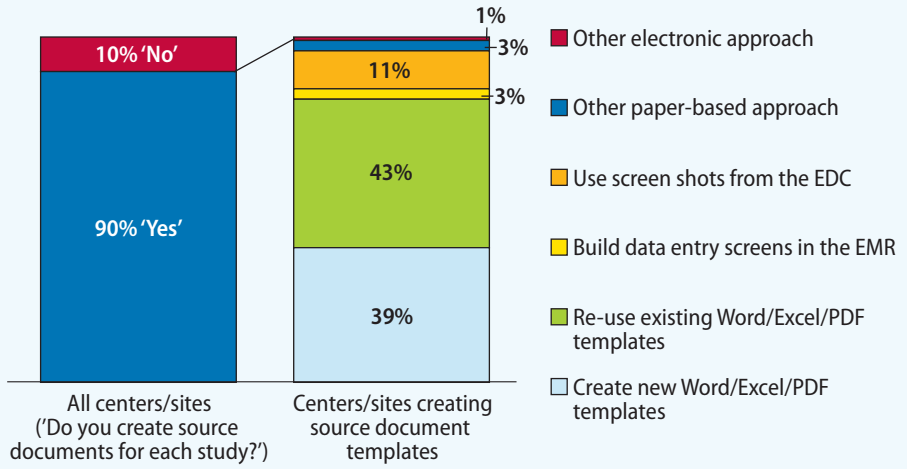
Manns said there are several contributing factors to the problem. These include a fear of technology, lack of interoperability, resistance to change and a fear of data security issues.

Most (79%) respondents said they would find it helpful to record the study-specific source data electronically instead of having to re-enter the data into an EDC during the patient visit. Among those who feel that recording study-specific source data electronically is not helpful, most felt that data entry and looking at a computer during a study visit takes time away from the personal interaction with patients and tends to lengthen the study visit time given all the activities necessary during the visit.

"It's important to take a long view in solving the eSource interoperability challenge," said Ed Seguine, CEO at Clinical Ink.

"EDC systems, as designed today, primarily meet the needs of statisticians to collect and organize data for analysis—they have nothing at all to do with the protocol workflow required to actually see a patient," said Seguine. "Systems that are flexible enough to actually help sites with the workflow of seeing a patient and capturing the full spectrum of protocol-required clinical trial data are what is necessary."

Source document template for each study



Source: CenterWatch, Clinical Ink, SCRS 2017; n=656 Research Centers

Breaking the aversion to change

Hugo Stephenson, M.D., executive chairman of DrugDev, cited results from a DrugDev survey that mirrored some of the CenterWatch survey findings. Stephenson has spent the last 20 years as a physician investigator (PI). He said that EHR use outside the U.S. is even lower at 52% in Western Europe and only 43% in South America.

"I'm surprised and disappointed there hasn't been much improvement in the entire clinical trial process, including the state of data collection and the technologies available to sites. The use of this information for research is still very much in its early days," he said.

According to Dr. Stephenson, part of the problem is basic organizational aversion to change and how the cost of change is managed and shared. "When you're dragging a conservative industry into the modern age, you will meet with fierce resistance. Pharma is no different," he noted.

"The high cost of hardware to create EDC platforms is a cost that gets transferred from the sponsor to the site," he said. Stephenson suggested that a solution would be for sponsors to increase site reimbursements for additional data entry time and the deployment of mobile devices. "Fees," he said, "have not been adjusted in years."

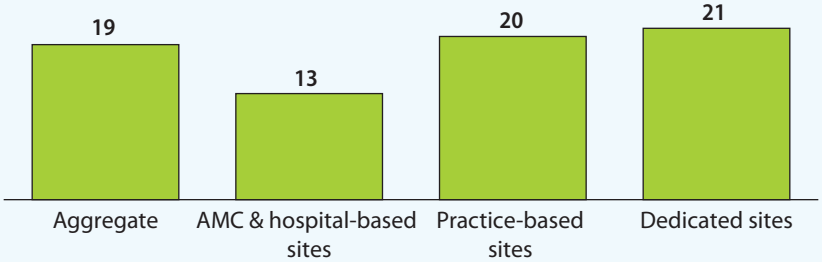
"Each different practice type has its own EMR ecosystem that makes integration even more difficult," Dr. Stephenson explained. "Large academic hospitals and networks have big systems, highly customized to their own needs—so two networks running the same software may still manage data in different ways."

According to CDISC's Kush, there have been many starts and stops in creating a common, shared, intraoperative data standard. Kush cited pharmaceutical company reluctance to embrace new standards as a major adoption barrier.

"There are a lot of politics around this issue. We need to move beyond demonstra-

Time spent creating a source document template for each study

Mean number of hours



Source: CenterWatch, Clinical Ink, SCRS 2017; n=656 Research Centers (n=161 AMC/Hospitals; 254 Practice-based; 218 Dedicated and 23 'Other' (not included))

tion projects and do this for real," Dr. Kush told CenterWatch.

She said there have been encouraging recent developments. A consortium of 19 big pharma companies has come together to find ways to help improve a common data reporting platform. And in November, the FDA issued Binding Guidelines that require all data submitted to the FDA meet CDISC standards.

In May 2016, the FDA issued a 12-page draft guideline to promote the interoperability of EHRs and electronic systems supporting data collection in clinical trials. In a recent development, President Obama also signed the 21st Century Cures Act. One of the main goals of the law is to facilitate the swift development of new drugs and medical devices. Many of the details of the law have not yet been released, but it is not a stretch that the longstanding issue of common data gathering platforms and interoperability might be addressed.

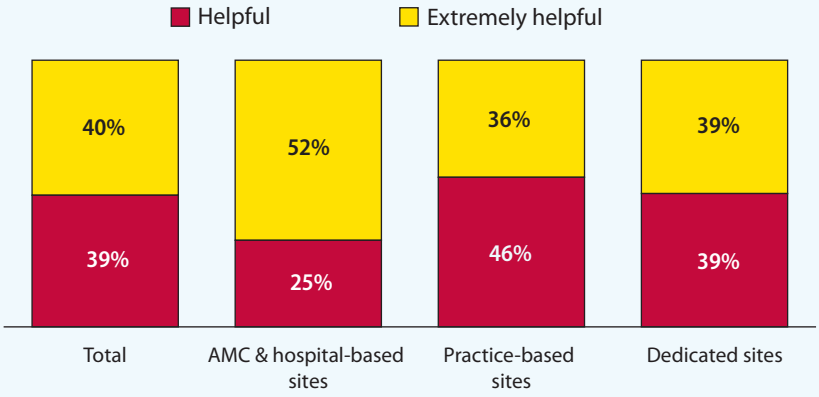
"I'm incredibly excited about the 21st Century Cures Act," said Glen de Vries, president at Medidata Solutions. De Vries said he helped start the company because he didn't like the amount of time he had to spend manually collecting clinical research data.

"There is a huge untapped potential in clinical trials, with new technology using nontraditional tools," he said. "Wearables and other mobile sensor devices, for example, offer so much upside for patients to help us figure out what's good in development."

Over the past 15 years, the industry has made some progress reducing the data collection burden on sites, but the ultimate solution is to create a system of automated data transmission. "Our industry has to get over the idea that a person needs to be there when data moves from one system to another," de Vries explained. "That's just not a modern way to share and manage data."

Most centers/sites would find eSource data collection during patient visits helpful

Percent indicate 'Helpful' and 'Extremely Helpful'



Source: CenterWatch, Clinical Ink, SCRS 2017; n=656 Research Centers (n=161 AMC/Hospitals; 254 Practice-based; 218 Dedicated and 23 'Other' (not included))

"Sites are moving away from paper, but we still see a lot of efforts that sites have to make entering duplicate data into multiple systems."

—John Manns, senior director, Clinical Innovation, PPD

The rubber meets the road

Mann of PPD advocates that a big part of the solution is more time spent talking to investigative sites to understand what is actually happening and what investigative sites need.

"CROs and pharma need to listen to the sites so we do not create undue burden for them," said Manns.

DrugDev's Stephenson suggested that sites be viewed as part of the solution, not the cause of slow adoption.

"There's a limited pool of active sites carrying much of the drug development activity on its shoulders. We have to make it easier and more attractive for sites and physicians to complete research activities," he said. "Sites have different needs and challenges depending on the setup, culture and the country's regulatory requirements. But no matter where we are located, sites are critical to running a global, multicenter trial. They're the engine room of the clinical trial."

John W. Mitchell is a published freelance writer and novelist (Medical Necessity) in a wide range of fields, including healthcare. He is a retired hospital CEO. In 2009, Mitchell and his team were named "Top Leadership Team in Healthcare for Mid-Sized Hospitals" by HealthLeaders press. Email john@snowpackpr.com.