Denise Myshko

Technology in *Clinical* TRIALS

Data are the lifeblood of a clinical trial, yet more information isn't always the answer to improved productivity.

Data are the glue that hold clinical trials together, says Colin Hill, CEO, president, chairman, and co-founder of GNS Healthcare.

"Data are being created at an unprecedented rate — by pharma, academia, providers, payers, and government — but the value that is being created is not commensurate with the volume," he says. "One problem is simply getting in one place the data that are needed to solve a particular problem. Having the right standards in place and the right structures that allow data to become liquid and move between entities are key to solving this problem."

The ubiquitousness of powerful technology will make processes more efficient and provide clarity into what's actually happening across a sponsor's portfolio of trials, says Rick Morrison, founder and CEO of Comprehend Systems.

"We're now at a point where the industry needs to start consolidating, or relying on technology that connects these systems instead of creating new silos," he says. "Being able to leverage existing clinical trial data from legacy studies will become extremely important."

Today's systems are siloed in terms of functionality and, therefore, very few are connected, agrees Andrea McGonigle, managing director, life sciences, at Microsoft.

"It is important to realize that the clinical trial is a process, starting with the protocol, and the CTMS system, continuing with the clinical investigator portal, the trial master file and so forth," she says. "In a process-oriented approach, the CTMS system should be able to automatically provision the clinical trial portal for participating investigators and research associates, including automating the on-boarding process, and the portal should be fully integrated with the trial master file. The advantages are obvious: business agility, increased quality and compliance, elimination of redundancies, and increasing user satisfaction."

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>
> **DANIEL O'CONNOR** / InnovoCommerce

Daniel O'Connor, CEO of InnovoCommerce, says sponsor organizations are seeking centralized and easy to set up and manage portals because clinical trials are becoming increasingly complex and global in nature.

"Additionally, many companies are cutting back on personnel while implementing more outsourcing programs," he says. "A technology solution is key to facing these persistent and crucial challenges. First and foremost, sponsors have heavily invested in several underlying e-clinical technologies over the years, including EDC, CTMS, IVRS, EDMS, and CDM. Each business application provides its own set of legacy logic, human processes, and regulatory drivers. Providing coherent, centralized access that is easy to use as well as available to external participants remains a tough challenge."

Mr. O'Connor says technology solutions alone are not sufficient.

"Visionary changes in sponsor organizations that reshape how clinical organizations work in this fast-changing, dynamic, and global industry are required," he says. "As these factors are addressed, a clinical and investigator portal solution can be a powerful catalyst to drive a centralized and standardized approach to managing complex global clinical trials. Focused and visionary leadership, process changes, and adoption of flexible and agile platforms must be combined in ways to more effectively and efficiently manage global clinical trial programs."

Bill Cooney, president and CEO at MedPoint, says a continuing challenge is to deploy interoperable e-clinical systems that work with each other to exchange data and harmonize activities.

FAST FACT

75% OF RESPONDENTS HAVE SOME EXPERIENCE WITH THE USE OF EPRO; 76% ARE UNFAMILIAR WITH THE REGULATORY GUIDANCE FOR THE USE OF THE TECHNOLOGY.

Source: Premier Research

"Interoperability goes hand-in-hand with modular systems and cloud-hosted solutions, which are two major trends in e-clinical technology," he says. "Virtually every major e-clinical provider professes to be interoperable, but despite lofty claims and many legitimate advances, there's still work to be done. Today, most drug developers use a patchwork of unconnected e-clinical systems, sometimes from the same vendor. CDISC provides a good foundation of data standards for interoperability, but the e-clinical community must double up on its efforts to field technology that works together to support clinical trials."

There are several advantages associated with linking the eTMF directly to CTMS, says Dan Glass, VP, e-content management, at Y-Prime.

"First, the integration greatly reduces the labor associated with data entry into CTMS associated with document acquisition," he says. "Second, the direct integration may also enable companies to track the cycle time of critical site regulatory documents for each site. This cycle time is a key performance indicator for rapid study start up."

Among the biggest challenges related to implementing technology in clinical trials include availability of technology in certain regions of the world, says Joe Bedford, director of marketing at Almac.

"While most clinical trial sites today have made great advances in terms of having access to computer and Internet-based technologies, there are still certain areas of the world that struggle in this regard," he says. "There are even more that struggle in terms of having access to advanced laboratory testing facilities. Use of central laboratories helps ameliorate these issues in most cases, but not all, as some samples need to be collected and processed locally and quickly."

John Hudak, president and founder of Criterium, says electronic medical record (EMR) systems have become the standard at many sites, but the technologies to capture clinical data still require transcription from the EMR system to the clinical application system, i.e., EDC, IVR, and IWR.

"Monitoring of those transcriptions is still a clerical task," he says. "EDC provides an opportunity to collect data more efficiently, but delegates the data entry to expensive medical staff whose training is in managing patients, not data entry. Because EMR systems include confidential information, the monitoring becomes more complicated.

"And as sponsors and CROs develop more experience with electronic systems, they feel more compelled to dictate the design of EDC/IVR/IWR systems, thereby forcing the technology experts to program in ways that are not efficient, and thus increase the cost of these applications," Mr. Hudak continues.

Michael Kuss, VP of analgesia at Premier Research, says one of the biggest challenges concerns the confusion that surrounds the use of ePRO technology in clinical trials for the development of new drugs.

In fact, a recent survey commissioned by Premier Research revealed that while three out of four respondents (75%) have some recent experience with the use of ePRO in clinical trials, about the same number (76%) are confused or even unfamiliar with the regulatory guidance for the use of the technology.

The other challenge with ePRO is that despite the fact that nearly all respondents (98%) indicate that they were likely or definitely going to use ePRO technology for their future clinical trials, 45% also cited ePRO's high cost as the primary obstacle to its actual adoption.

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JOHN HUDAK / Criterium

Mr. Hudak says there is an inherent cost to using these systems that includes the operators of these custom, real-time applications.

"While sites are better prepared to embrace real-time technology, sponsors are more willing to pay the incremental costs," he says. "CROs have incorporated technology into the site's monitoring and data management processes, but getting the users to understand how the various technologies work together is difficult," he says.

Tim Davis, CEO of Exco InTouch, says the effective use of technology to support clinical trials is increasingly becoming an accepted way of engaging in real-time patient communication and data capture.

"As access to technology becomes more widely available, demonstrated with the increase in availability of the Internet, teamed with the rapid growth of portable devices, end users now have an expectation of direct interaction with healthcare providers and clinicians," he says.

A new challenge when conducting clinical trials is to overcome data security concerns through proven positive experiences.

"The use of secure platforms designed specifically for healthcare applications that have built-in compliance prompters and adhere to global data protection regulations including HIPAA and Safe Harbor could transform the way trials are conducted," Mr. Davis says.

"Beyond this requirement for security and proof of data protection, it is imperative to ed-

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>
> **MICHAEL KUSS** / Premier Research

ucate the industry about the value of technology through real-life examples and, as a result, build awareness that effective solutions can provide users with simple, familiar, user-friendly technology that can help prompt adherence," he says.

The Cloud in Clinical Trials

Our experts say the future of clinical trials technology requires a process-oriented, standards-based approach from the ground up, built on a cloud-ready technology platform that shares as many foundational components as possible, for example, workflow, forms, search, collaboration and social, identity management, etc.

"The cloud has fundamental transformational capabilities in doing things better, faster, and cheaper," Ms. McGonigle says. "But the cloud is not a panacea either. The cloud has to be trusted and compliant and ensure that data governance and privacy issues are maintained at all times. Not all aspects of cloud computing in the clinical trials continuum are subject to validation and 21 CFR Part 11 compliance, but key components such as the trial master file are."

Ms. McGonigle says it is important to note that the cloud can mean many things, such as public cloud, private cloud, software as a service (SaaS), platform as a service (PaaS), or infrastructure as a service (IaaS).

"An ideal solution should support all modalities and be able to support a hybrid mode, such as private cloud for the trial master file, and software as a service for the investigator portal, and present a seamless and user-friendly environment for all stakeholders."

Software as a service models have been used for many years in the pharmaceutical industry with the eRDC (CDMS) platforms, says Andy Lee, deputy head of clinical sciences and operations at Sanofi.

"The cloud is the continuation of this trend, bringing additional functionalities in the ability of the sponsors to manage the elasticity of their platforms, adjusting the computing capacity with the demand of the R&D organization," he says. "Overall the main driver here is the cost optimization and the opportunity to switch from a fixed-cost model to a variable-cost model. This allows aligning the clinical information system costs with the actual clinical portfolio."

Mr. Morrison says the cloud offers sponsors a way to scale costs with usage and need. This on-demand scaling can lead to drastic savings and enables sponsors and CROs to build much more scalable infrastructures, resulting in cost and time savings.

"Cloud computing will help revolutionize all aspects of R&D," he says. "The power and scale of cloud computing means that scientists can perform deep analysis that wasn't possible earlier."

Sheila Rocchio, VP of marketing and product management at PHT, says many clinical trial system providers are moving pieces of their applications to the cloud and becoming more cloud-like, although some may argue that the key benefits of cloud computing, including reduced costs, metered usage, and metric-based pay-as-you-go options, have yet to be achieved in the clinical trial market.

"When leveraging the cloud for global clinical research applications, ensure the system has evidence to support all aspects of regulatory compliance, including the required set of security and privacy features mandated by global regulators as well as internal SOPs and those of partners including sites and CROs," she says. "Many cloud applications have less ability to be customer-specific than other software-enabled services, and the cost benefits of the cloud need to be compared with the many customer-specific requirements that are very common in most existing software applications widely used in clinical development."

Mr. Glass says the use of cloud-based systems to support clinical trials is most successful when sponsors are willing to accept standard features and functions of these types of systems.

"Extensive configuration and/or customization significantly delays the implementation and adds significant cost," he says. "Increasingly, sponsors are seeing the value of implementing an entry portal that serves as the landing space for all users of cloud solutions. This single point of entry also facilitates compliance."

John Blakeley, chief commercial officer at Greenphire, adds that the adoption of cloud-based clinical payment technology can save significant time and money in the trials area.

"These approaches can reduce the time and manpower required to manage what has historically been done with paper and pen," he says. "The technology approach drives transparency into the process for all stakeholders and allows sponsors to more effectively service the financial needs of their clinical research site partners."

Mr. Lee says the key success point continues to be the quality of the service offering in terms of platform performance and security.

"As the cloud computing model is gaining momentum, new clinical applications are made available on the cloud by the main software providers," he says.

Mr. Davis says effective and well-thought out use of the cloud in clinical trials holds the potential to considerably transform data collection and storage processes.

"The cloud overcomes a number of logistical issues with the transfer and storage of clinical data through allowing remote access to data stored on physical servers, which is particularly important in global trials where research is often conducted off-site in remote locations," he says. "But successful adoption of the cloud by the industry is dependent on overcoming the perception that data access through the cloud is subject to greater risk than traditional methods of data management and embracing the myriad benefits it can offer." PV

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