BY DENISE MYSHKO

Technology KEY FOR GLOBAL Development

Experts say technology has the potential to help pharmaceutical sponsors address communication challenges, manage data effectively across geographic regions, and ultimately speed processes.

"Communications technology is core to global development," says Brad Thompson, Ph.D., chairman, president, and CEO of Oncolytics Biotech.

"The ability to shunt data back and forth in real time and the ability to interface with people in the office in real time are basic infrastructures," he says. "Once these goals are achieved, the distance and the remoteness disappear."

Tammy Ice, director of patient recruitment and investigator services at INC Research, says technology has vastly changed the landscape of drug-development processes in recent years.

"The increased ability to deploy EDC systems on a global basis has led to increased efficiencies in the management of participating study sites," she says. "EDC systems enable study teams to monitor site progress in close to real-time, react to potential data issues more quickly, and be better prepared for planned on-site visits. In some cases, monitoring frequency can even be reduced as a result of proactive in-house site management via an EDC system, which can lead to bottom-line resource and cost efficiencies."

DATA TECHNOLOGIES

Tomás Bocanegra, senior VP, clinical development, at Daiichi Sankyo, says technology is crucial in global drug development to track study performance metrics, including site initiation, patient recruitment, sharing of recruitment aid materials and tools, and monitoring the quality of data.

"Technology allows sponsors to track and predict screening rates and enrollment close dates more accurately, limiting the costs associated with over-enrollment, drug supply packaging and distribution, and having a database to assess protocol and program feasibility for future studies," he says.

"The acceptance of EDC has greatly enhanced how sponsors and investigators manage and track information across geographic regions and time zones," Mr. Bocanegra continues. "Real-time data entry allows more accurate tracking of information and helps to identify and react more effectively to safety signals, and assess ongoing performance and outcomes. Access to real-time information provides transparency by showing performance measurements to identify inefficiencies, which is critical in maintaining good quality throughout the development process."

Sandra DiGiambattista, project director, clinical operations, peri-approval services, at Covance, says by making research information available through the Internet, sites can reach a wider audience base from which to recruit patients.

"Prospective patients and their families are more informed about the global medical care available and alternative solutions," she says. "This widespread information can speed along the patient-recruitment process by offering inclusion/exclusion criteria for actively enrolling trials. Interactive voice response system (IVRS) technology is used in almost all clinical trials allowing more efficient tracking and drug allocation processes.

"When selecting sites, electronic medical records can be used to predict site-enrollment potential more realistically," she continues. "Electronic medical records are also used around the world for more efficient doctor-to-doctor referral processes. As technology continues to develop with EDC, patients are more efficiently screened and more accurately enrolled in trials than ever before."

COMMUNICATIONS TECHNOLOGIES

Technology can address some of the communications challenges of conducting trials globally.

Patrick Lindsay, executive VP of United BioSource, says technology has enabled suppliers and sponsors to establish far more sophisticated interactions, enabling the two groups to bridge time-zone problems through the use of Web-based study management portals, provide real-time access and analysis of data from anywhere around the world, and bring teams closer together through the use of video conferencing or instant messaging.

"By flattening the time element, technology allows a sharing of sensitive program data in near real time across many complex program domains, thereby streamlining interactions and communications," he says. "As study designs become more complex and pressure increases to make efficient decisions, the industry relies on technology to consolidate data quickly from multi-modal sources and scan the data real-time for potential issues based on pre-defined criteria. An automated alert process, for example, can then raise red flags virtually immediately."

Bruce Garrett, M.D., president and CEO of Global Research Services, says it is not possible to run a multinational trial, whether it is on one continent or more than one continent, without state-of-the-art technology.

"In the age of the Internet, sponsors, CROs, and study sites can now manage data capture and day-to-day operations via the Web," he says. "As with global operations, technology is absolutely necessary for all daily interactions, from e-mails and Webcams to VoIP system."

Technology continues to grow and fill voids as new trends develop, says Raymond Panas, Ph.D., director of international clinical development, Sucampo Pharmaceuticals.

"Electronic records are becoming more and more popular at many institutions," he says. "Using key words and disease or drug codes will enhance patient-recruitment options. Creating electronic interphases between patient records and EDC systems may enhance the ability to transfer data between systems and minimize transcription errors between records. The Internet and Webportals continue to be used more frequently in clinical trials. With increased use of mobile phones, personal organizers, and other electronic equipment, technology may enhance the ability to capture real-time data for diaries and patient assessments."

Dr. Panas says with the use of Webmeetings, Webcams, and other technologies, individuals from across the globe can interact on various levels for communication and sharing of data.

"As much as we work across continents and oceans, the biggest hurdle can still be time zones," he says. "The time difference between Boston and Seoul is 14 hours. While technology can help us communicate, the time zones still mean it is likely an inconvenience to someone. As more people around the globe are added, the inconvenience grows."

Vijai Kumar, M.D., president and chief medical officer of Excel Life Science, says sponsors are expecting more than weekly update reports.

"They want access to daily data on the progress of their studies, including access to operations employees in the field and working in the trenches," he says. "Beyond tracking reports and weekly update meetings, sponsors are expecting all study-related operations personnel to be available by smart phone and computer almost 24/7. In addition, companies are investing greater resources in the home countries of their clients. Sponsors are expecting client service, medical, and regulatory expertise available at a time and location that is practical for them." ✦

USING TECHNOLOGY TO CREATE EFFICIENT PROCESSES FOR DRUG DEVELOPMENT

To date, technology priorities in drug development, particularly clinical development, have largely focused on the electronic collection and cleaning of case report form data (i.e., EDC). While enjoying the benefits of getting cleaner research data faster, EDC has not produced fundamental improvements in research and development; existing technology does not address the multiple tiers of inefficiency in discovering and developing novel therapies. To see improvements that directly translate into better bottom-line performance, four technology-related areas will rise to the center of attention:

MACHINE-READABLE RESEARCH SPECIFICATIONS

Electronically structured protocols, analysis plans, and other common objects that will enable automation and reuse of research processes and assets. For example, an electronic representation of a study protocol will be used to automatically configure data collection environments and analytical systems, reducing the time, effort, and variability associated with implementing clinical studies. Whereas existing data repositories store data without its associated contextual information (e.g., what was the patient doing when this measurement was made), electronic study specifications will provide the semantic bridge between individual data items and their respective clinical contexts, enabling newer software to more easily do tasks that today require human intervention.

DATA-TAMING SOFTWARE

Through progress in national health initiatives, public/private/academic research partnerships, and electronic medical and patient records, significantly larger volumes of information will be available to research institutions. The size, geographic diversity, and increased complexity of these data will require the use of more sophisticated data integration, aggregation, and analytical methods in order to derive insight and make better medical decisions. Institutions will gain market advantage based on their ability to derive competitive insights from this growing ecosystem of medically related information. As such, advanced analytics will rise in prominence in terms of both technology architecture as well as organizational competencies.

PERFORMANCE MANAGEMENT

Using both clinical and operational metrics from prior and current research efforts to reduce the time, work volume, and resource requirements for completing clinical research programs. For example, institutions will make more educated decisions around site selection and data collection instruments based on their prior performance with respect to data timeliness and quality.

PORTFOLIO OPTIMIZATION

The adoption of multivariate analytical methods to determine the best investment options across product portfolios. Through the use of advanced forecasting, modeling, simulation, and other predictive analytics, executive decisions will be based on a clearer understanding of the correlations between external market dynamics and their specific projected portfolio performance.

Source: Jason Burke, Worldwide Director, Health and Life Sciences, SAS. For more information, visit sas.com.