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BY ROBIN ROBINSON

Keeping Pace WITH THE CHANGES IN CLINICAL OPERATIONS

The clinical operations function is a crucial element in the overall success of a pharmaceutical organization, and like the rest of the industry, the individuals who are on the clinical front line are facing pressure to do more, faster, better, and of course, more cost-effectively. PharmaVOICE asked industry experts to find out how the changing environment is affecting clinical operations.

Managing the Challenges

The challenges facing today's clinical operations director are many, including accurately measuring site performance, managing partner relationships, and overcoming the communications barriers between clinical and data operations. Our experts discuss these and other hurdles that are all part of the evolving clinical process.

GOTTING-SMITH. ASTRAZENECA. We have entered an era of radical change for clinical program delivery. The pharmaceutical industry is experiencing pressures on price, earlier entry of generics, and lower output of new approved medicines. R&D spending has increased 70% during the last decade. Delivery of the clinical programs has a critical impact on both the time to delivery and the cost required to develop new medicines. The focus on improving clinical operations and finding new models to deliver has intensified over the last five to seven years. Many options for different elements of operational delivery have emerged, ranging from centralized data management in low-cost countries to offshore options for medical writing and safety surveillance. The large size of clinical programs, new technological solutions, new requirements for translational science, and the conducting of studies across 20 or more countries has resulted in a large, global, and complex infrastructure that is expensive to manage. The main requirements for new operational models are, therefore, centered on consolidation, driving adherence to simple standards, accessing the best and most experienced talent, and finding cost-effective options while maintaining quality.

GORDON. KING PHARMACEUTICALS. Within the clinical operations segment of the pharmaceutical industry, improvements in availability of trained human resources are needed. The identification and recruitment of personnel with the appropriate skills and experience are enormous challenges. Currently, training in the clinical operations function occurs primarily in-house, because there are few academic programs preparing people to work specifically in this field. Most of the candidates for clinical operations who we see have a sound scientific knowledge base and come from a pharmacy, nursing, or scientific background. Yet, when a person assumes a clinical operations position, there is often a learning curve in developing the necessary skills for the position. Not only is it a challenge to identify individuals who know and understand the clinical operations process in the United

DR. KAREN GOTTING-SMITH
ASTRAZENECA

▶ The focus on improving clinical operations and looking for new models has intensified over the last five to seven years.

States, but it is increasingly difficult to find individuals with experience in global clinical studies, where a number of studies are now conducted.

DOYLE. KFORCE. There are several challenging areas facing today's clinical operations managers. First, there is a need to focus on cycle times and how to improve efficiencies within site management, which will positively impact site and study collaboration. If processes can be improved and errors can be reduced, then collectively we can improve the industry as a whole. To accomplish these goals, we can look to other industries, such as the IT and automotive industries and leverage the process improvements they have gained by fully outsourcing specific functions to strategic partners. Patient recruitment and improved investigator performance are two other critical success factors to any trial. There is a renewed focus on measuring site performance in terms of recruiting patients and developing better relationships with those who are participating. By applying lean operational processes to measure and improve efficiencies, we can improve the quality of life for monitors and directly impact cycle times as institutional process redundancies are eliminated. Managers should be analyzing current processes to understand if assigning monitors to sites instead of trials might be a more efficient way of resourcing. For example, they should evaluate whether it makes more sense to send multiple monitors to the same site to monitor multiple studies, or does it make better sense to send one monitor to the same site and align them across therapeutic areas for greater efficiencies. Improving the myriad technology systems used for communications and reducing the instance of duplicate data entry will reduce the overall time consumed in redundant processes and also provide greater visibility to lead indicators, rather than reacting to lag indicators. Retention of staff is another critical element in the overall cycle time of a trial, and empowering front-line teams to achieve operational excellence and execute accordingly will be a powerful tool in reducing turnover.

EVANS. ESSENTIAL GROUP. I believe there are two major areas for improvement in the clinical operations space. One is to improve turnaround times of approved monitoring reports via electronic reports with e-signatures. CRAs must be able to access a Web-based CTMS (clinical trial management system) database to import and export data while at the site. It is also important that they have the ability to generate the monitoring report in real time during the visit. By doing this, monitors could decrease turnaround times by days or even weeks compared with traditional methods. This not only improves quality but in many cases could favorably impact site payments. Sites are motivated to enroll more patients when payments are timely. The other aspect involves improved CRF or EDC module designs that minimize redundancies in data collection, minimize collection of unnecessary data points, and are intuitive to the study coordinators while still meeting the needs of data management.

THOMPSON. INVENTIV CLINICAL. The industry is in dire need of common tools and metrics that can be used across studies and sites to optimize overall project management. Specifically, we need common metrics that can be tracked on both a historical basis to ensure site/study productivity as well as during the actual conduct of the clinical trial to ensure that corrective actions can be put in place before a clinical trial is in jeopardy.

GORDON. KING PHARMACEUTICALS. There is also a need to refine EDC, a tool that has dramatically advanced in the last decade allowing site clinicians to capture data in real time. Many challenges remain in optimizing the production of these tools accurately and expediently. Moving toward a system based on EDC allows information to be better integrated and more efficiently downloaded at the end of the study, but improvements are needed in study start-up requirements. In addition to EDC use by clinicians, recording of patient data electronically has improved accuracy by allowing patients to efficiently report progress in real time. This concept has evolved substantially over the past 10 years, but there is room for improvement in the development and validation of patient-friendly data capture systems.

STEFANZICK. CRITERIUM. There is always room for improvement in communications and workflow, and that is an ongoing process. A clinical operations manager needs to be consistently attentive to the systems, the people, and how they interact with each other in each study. For instance, studies should have teams of in-house monitors or clinical data liaisons who communicate with monitors in the field. Breaking down the division between clinical

and data operations improves communications, speeds up the data flow, and maximizes the use of technology for better data management and reporting.

BUTLER. APTUIT. Integrating operations to remove the inefficiencies that exist because of traditional operational silos is a necessary improvement as the industry works to eliminate the obstacles and redundancies that slow drug development and clinical operations. Integration at an operational level requires drug developers to leverage available scientific expertise and organize project teams in such a way that scientists ordinarily involved in separate aspects of the project collaborate at an early stage to anticipate and address potential inefficiencies. By taking advantage of the synergies that are inherent in the scientific process, we not only anticipate and overcome organizational obstacles, but also gain better insight into the drugs being developed, see improved safety data, and advance drugs into the clinic more efficiently.

GOTTING-SMITH. ASTRAZENECA. Techniques that focus on the voice of the customer and analyze current in-house capabilities and activities are just a couple of approaches we are using to determine which activities may be

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RONALD S. WAIFE. President, Waife & Associates Inc., Needham, Mass.; Waife is a management consulting company focused on the clinical-research process for biopharma, devices, and CROs. For more information, visit waife.com.

ELEANORE DOYLE
KFORCE CLINICAL RESEARCH

▶ The only way to better manage data and results is through continued focus on standardization using CDISC or HL7.

RONALD WAIFE
WAIFE & ASSOCIATES

▶ Most changes being pursued today are adapting 20- or 30-year-old practices to modern day realities. Instead, we encourage the industry to re-examine clinical development.

outsourced/offshored or remain in house. Overhauling the entire drug-development process is more difficult since ensuring we deliver a robust data set through classic phases of development to clearly determine the benefit/risk of new products is pivotal to regulatory agencies being able to approve new medicines.

WAIFE. WAIFE & ASSOCIATES. I would identify two widespread needs in the industry. One is to adapt clinical-trial execution properly to e-clinical requirements and possibilities, and two, eliminate nonvalue-added work, which is everywhere in clinical operations. I would also add that there is a need to rationalize outsourcing. What I mean is that there is a need to examine factually whether it truly and measurably makes sense to offshore, or use an FSP, or offload anything to either a nonpharma business, or any business that the pharma company does not control. Sometimes it makes sense to outsource and a lot of times it does not. Just like recent approaches to clinical operations reorganizations, outsourcing is pursued like fashion; fashions are supposed to change every season, which is great for the clothing industry, but not for pharmaceutical development processes.

Outsourcing Functions

Changes in responsibilities and outsourcing have created a more flexible, partnership-oriented, integrated function for the clinical operations head.

THOMPSON. INVENTIV CLINICAL. The increasing pressure to deliver clinical trials in a cost-effective but safe manner has forced clinical-trial sponsors and their partners to work in more of a partnership with monitoring plans and to address quality issues up front as part of the ongoing execution of the trial. This link between sponsor and partner requires flexibility from the partner to meet a variety of sponsor needs by providing trained staff who have the proper experience, training, and electronic connections to ensure proper clinical-trial execution and delivery of high-quality data. On the back end, more and more sponsors and partners are instituting a lessons-learned exercise to evaluate how well the team performed and what improvements can be made in the future. The industry is also learning the value of flexible workforces. The ability to scale-up and size down rapidly with experienced, trained staff is key to efficient and successful product development. Because of this trend, the roles and responsibilities maintained by the core staff are focusing on senior project management and a flexible workforce can be brought in to handle the responsibilities that can be outsourced. For example, medical writing, monitoring, and data analysis are tasks that can be outsourced to flexible work staffs without impacting study control and quality.

DOYLE. KFORCE. Many of the major pharmaceutical firms have moved to regionally based monitoring solutions that are either partially or fully outsourced. Monitoring needs to be approached in a top down and bottom up workflow analysis. As such, people responsible for site management can execute study plans and provide feedback to mutually evolve the workflow. Some pharma companies have outsourced study management, and we believe that this trend will only increase as companies seek to outsource more of their operational roles so they can focus on the science of developing drugs. Functional service providers are retaining more of the intellectual capital regarding site and study management as pharma companies outsource more of these functions.

GOTTING-SMITH. ASTRAZENECA. Historically, the pharma industry has used CROs to take on whole trials or certain activities for whole trials when the in-house capacity is already full. In recent years, this partnership has moved toward business process outsourcing. In other words, companies are stopping the activity in-house and are relying on a partnership with an external vendor to provide this particular service for all clinical studies. Examples of this include clinical data management, which several pharma companies now based in India through external providers. Interestingly, more than 90% of the decisions that have been made to offshore data management to an external vendor have gone to companies that did not have data management capabilities four years ago. This is a sign of just how rapidly the changes are happening. The types of activities that have been outsourced or off shored are data management, medical writing, statistical programming, biostats, and safety surveillance.

GORDON. KING PHARMACEUTICALS. Over the past few years, there have been a number of changes in the roles and responsibilities in the clinical operations function. EDC has been a primary driver for shifting workflow since many elements of data entry are performed at

the clinical sites. The processes for validating and querying data have shifted from manual review to the development of programs that identify potential errors and generate questions directed to the sites. Although EDC is needed to improve the efficiency of the development system, this is a change in the way that clinical-trial data have been captured and monitored over the years. This, in turn, has changed the investigator's workflow and responsibilities.

BUTLER. APTUIT. Information hand-off typically slows the process, and integrated project teams working in a collaborative environment from the very beginning of a project — instead of working across traditional drug development silos — reduce the time burned at the start of each stage. In practice, this means that there is a dedicated operations project leader, and not several project leaders across each operational area. Also, by setting up standardized protocols for precursor materials, data formats, and deliverable formats, scientists and others involved in a project can focus on advancing a molecule into the clinic rather than designing a new process once the project scope is defined. This does not mean that the processes are not flexible and nimble enough to accommodate the changing dynamics of any particular drug development project, but rather that the groundwork is in place to reduce the time required at these decision interfaces that typically slow the process.

WAIFE. WAIFE & ASSOCIATES. Most changes being pursued today are still adapting 20- or 30-year-old practices to modern day realities. Too often companies experiment with dramatic reorganizations and role changes without any particular grounding in an operational reality. We encourage the industry to re-imagine clinical development, which does not start from automating old processes but by designing fresh ones, based on fresh roles, which requires more courage from an HR perspective, among others.

Technology Influencers

According to our industry experts, technology solutions, particularly electronic data capture (EDC), have been the single biggest driver influencing the changes taking place in the clinical space.

GOTTING-SMITH. ASTRAZENECA. The advent of EDC for clinical studies five to 10 years ago was really the first major step toward significant changes for clinical delivery. The options for electronic data capture are now primarily Web-based, which has reduced the overall volume of data checking requirements for in-house staff to review and check the quality of data coming in-house on paper. More recently, the development of data review tools, new programming standards, publishing tools, patient reported outcome tools — the list continues — have all revolutionized the way we do our work. As a result, there are job descriptions that now exist in the industry that did not exist five or 10 years ago and I am sure this will continue to evolve. Also, new providers emerge each year to provide improved services to our industry — whether to streamline our payments to investigators, to ensure we comply with fair market value, or to match patients to the trials we have open. To date, the greatest drivers for change have been the efficiency and cost reductions gained from centralizing and offshoring data management.

GORDON. KING PHARMACEUTICALS. EDC has changed the role of data collection, making it more efficient for both patients and site investigators. As a result, the role of the data collector has evolved and requires a different knowledge base. The impact of patient and site electronic data collection is fairly consistent, both contributing to better data collection and process outcomes. As EDC continues to expand, many aspects of data monitoring can occur remotely. Of course, all of these changes increase the challenges for investigator sites in recruiting, training, and establishing optimal workflow to adjust to the changes in expectations.

DOYLE. KFORCE As trials have grown and migrated to global markets, the need for real-time project management metrics is crucial. Data that are held in multiple systems and are pulled rather than pushed to front-line teams are by definition less valuable than if the data were available in real time to allow for proactive corrections. EDC has and will continue to dramatically improve the process of data management, but the use of CDISC and HL7 standards, for example, is even more critical to improving operational efficiencies. If these standards are not in place, manual processes will simply become automated manual processes.

CHERYLE EVANS
ESSENTIAL GROUP

▶ In this global world, technology is the highest driver impacting speed and quality, allowing for improved program management.

MARY STEFANZICK
CRITERIUM

▶ Breaking down the division between clinical and data operations improves communications and maximizes technology for better data management.

EVANS. ESSENTIAL GROUP. EDC, IVRS, e-diaries, study Web-portals, scanning, CTMS, and central lab Web-access all have opened the visibility of field activity to the project team. In this global world, technology is the highest driver impacting speed and quality, allowing for improved program management and more rapid response times. Near real-time access to data and documents is available as never before. This provides clinical operations a window into quality measures and enrollment hurdles so that rapid and proactive responses can be employed. Technology solutions also enable global teams to rapidly exchange information and key learning across projects.

THOMPSON. INVENTIV CLINICAL. EDC and health record systems have offered our industry the opportunity to significantly change how we do business, focusing more on protocol compliance and patient safety rather than source data verification and query reconciliation. In addition, the access to electronic data opens up potential opportunities of having initial data reviews done remotely. This frees up valuable on-site monitoring time for protocol and regulatory compliance reviews.

STEFANZICK. CRITERIUM. EDC is becoming increasingly popular with sponsors and generally throughout the industry. What is often overlooked is that EDC by itself cannot provide real-time data; therefore it's often better for sponsors to combine EDC with an IVR system. EDC combined with an IVR system can provide real-time information that gives a sponsor the ability to make faster decisions. With trials becoming more global, it is important to have a good grasp of the culture and infrastructure of the regions in which the studies are being conducted, including making use of each region's most current technology. Well-designed protocols will take cultural and technological factors into account to guarantee a successful trial.

BUTLER. APTUIT. Modern drug-development technologies have enabled scientists to develop many more new drug candidates than technologies of the past allowed. With an increased number of compounds, we're also witnessing more poorly bioavailable drug candidates. Advanced technology has actually created a greater need for operational team integration than ever before. To effectively determine which drug candidates to pursue, pharmaceutical and biotechnology innovators must have a team in place, free of decision-making silos, to provide formulations that will work in development and during scale-up; minimize the delays in information hand off; and focus on the candidates that have the best possible chance of being commercialized. Information technology (IT) has also significantly impacted clinical operations. Even beyond pure data capture, IT has evolved to be an enabler of team integration by allowing real-time access to a project from anywhere in the world.

WAIFE. WAIFE & ASSOCIATES. All e-clinical technologies — EDC, ePRO, CTMS, IVRS, AES — impact clinical operational roles. The lack of recognition of the benefits they bring seriously hinders the efficiency gains expected by executive management, and the scientific/business benefits possible. For instance, EDC challenges all players in clinical-trial execution to re-examine long-held assumptions of responsibilities and process. And yet many, if not most, EDC adopters have only layered the technology like a veneer on a paper-based operational structure.

THOMPSON. INVENTIV CLINICAL. Medical thought leaders, clinical operations, and data management personnel must work hand in hand during the planning stages of a clinical trial to ensure that the data collected can answer the questions needed for today's and tomorrow's patients. Many times there is a rush to get to the first patient visit without adequate focus on the operational feasibility of the clinical trial or the data necessary to answer the critical questions. Sponsors and their provider partners need to work together to understand and agree upon the data points that are needed to answer the critical trial questions. Once this is decided, proper training of the site management staff on each therapeutic area and protocol is key to gaining clean, meaningful data. EDC systems can also allow the early detection of failures in the conduct of the study and the implementation of a contingency plan to avoid the collection of poor or invalid data. Objectives must be clearly communicated to the team, including the sponsor, clinical operations, and the sites. And common technologies, such as Web seminars, videos, or teleconferences, can be valuable tools to improve the teams' consistency and to communicate issues or changes in objectives.

BUTLER. APTUIT. EDC is the most significant advancement in managing clinical-trial data and results. In working with our pharmaceutical and biotechnology clients, advocating

Sound Bites From the Field

PHARMAVOICE ASKED INDUSTRY LEADERS TO IDENTIFY WHAT THEY BELIEVE IS THE GREATEST CHALLENGE FACING THE CLINICAL OPERATIONS FUNCTION TODAY AND DISCUSS HOW THAT DIFFERS FROM ISSUES FACED IN THE PAST AND WHAT NEW ONES MAY LIE AHEAD.

LARRY BROWNSTEIN, MBA, is Chief Administrative Officer of CRI Worldwide, Clementon, N.J., a clinical research company committed to helping find safer and more effective treatments to central nervous system disorders. For more information, visit criww.com.

"With increased competition among research sites, and more vehicles to reach potential patients, the most significant challenge has become how to recruit the best possible patients in the most efficient and timely manner. In the past, sites could 'speculate' as to the expected rate of enrollment on a trial. With increasing costs and pressure on sponsors, sites are now being held accountable in delivering on stated timelines. We are integrating new technology, and closely linking our investigators with the community, to share information regarding ongoing and upcoming clinical trials and to provide complete accessibility, including transportation, evening hours, and around-the-clock access to physicians. In the future, sponsors will require sites to adhere even more strictly to enrollment timeline projections. Performance metrics will drive premium pricing with top performers, and exclude underperformers. Ultimately, sponsors will be looking for 'super sites' that can recruit large numbers of patients reliably at lower costs."

REBECCA CAUSEY is VP of Clinical Development Operations Americas at INC Research Inc., Raleigh, N.C., which is a therapeutically focused CRO with a trusted process for delivering reliable results. For more information, visit incresearch.com.

"Clinical operations drive increasingly more complex drug-development programs today than in the past. Organizations must be seamlessly global as the quest for finding appropriate patient populations within condensed timelines has grown more acute and expanded the geographic footprint that must be managed to meet that need.

Additionally, regulatory scrutiny has increased, which is driving the need for improved attention to GCP/ICH compliance and data quality. Clinical operations are challenged to constantly evaluate processes and seek improvements to ensure consistency and expediency from team members and investigators across the globe to excel and deliver to customer expectations. One can only guess what risks and challenges we will face in the future, but further upheavals in global conditions, affected by economic, political, and even religious forces will surely play a role. Clinical operations professionals must stay abreast of current events and their impact on lawmakers, corporations, physicians, and the citizens we ultimately serve to appropriately address risks and continue to succeed in bringing new treatments to market."

ROBBIE FRANKS, RN, BSN, is VP of Clinical Operations at Trio Clinical Research, Durham, N.C., a clinical research services company supporting the pharmaceutical, biotechnology, and medical-device industries in their quest to bring novel products to the market. For more information, visit trioclinicalresearch.com.

"Maintaining the talent pool of experienced research professionals is one of the greatest challenges in clinical operations today. Years ago pharmaceutical companies had their own employee pool of monitors and project managers. They gained therapeutic expertise and established and maintained strong relationships with the study sites throughout a clinical development program. There was a shift away from this employee model with the increasing number of mergers/acquisitions as well as growth in the number of biotechnology companies. Site relationships, among other things, were no longer a priority. With the growing number of studies and the competition for sites and patients, companies have realized the value these strong site relationships bring to their organization. Companies are once again demanding experienced, therapeutically aligned staff for their projects."

RENATE GAST-HEIMANN is Corporate VP of Clinical Operations, Clinical Research Services, at Parexel International Corp., Waltham, Mass., a global services organization that provides expertise in integrated clinical development, medical communications, and regulatory affairs, as well as technologies to expedite time-to-market. For more information, visit parexel.com.

"The clinical operations function has faced growing complexity over the past decade because of changing markets, varying healthcare systems and standards of care, and increasing regulatory requirements. At the same time, clinical research has experienced an intense period of global expansion, migrating from a few core hubs to diverse geographies around the globe, including Eastern Europe, Latin America, and the Asia-Pacific region. The industry is entering a new phase where these emerging geographies are becoming established markets. Because of this globalization, many challenges and opportunities exist for clinical operations. There is increased demand for qualified clinical sites and research staff. There is also the need for further standardization of processes and a framework that allows for consistency across geographies, while meeting local requirements. Additionally, fully integrated e-clinical technology platforms need to be implemented, as well as greater automation for certain components of study and site management.

Overall, to be successful in this new era, sponsors will need to turn more to outsourced partners with the capabilities and expertise to provide a fully integrated, global study team with in-depth local knowledge. Looking forward, there will be increasing demand for proactive planning, risk mitigation, and knowledge management in the clinical operations function. Additionally, there will be greater focus on performance management and governance structures."

BILL GWINN JR. is VP, New Product Development, at Inclinix Inc., Wilmington, N.C., an enrollment CRO and resource for clinical-trial recruitment solutions. For more information, visit inclinix.com.

"The greatest challenge to the clinical operations function is getting trials finished on time, a classic dilemma for the industry. Most industries do not even have terms like 'rescue mode,' for when trials run late. There is intense focus on developing new drugs and it is getting even harder to find patients. In response, the operations role is adapting. There is greater use of outsourcing, more specialization, and greater use of quantitative methods for better planning. For instance, disease prevalence maps can identify concentrations of patients so trials can 'fish where the fish are' in new patient recruiting. Everyone in the industry must be prepared to learn new methods."

MICHAEL HARTE is Senior VP, Strategic Accounts, at etrials Worldwide Inc., Morrisville, N.C., an e-clinical software and services company that provides services to pharmaceutical, biotech, and contract research organizations. For more information, visit etrials.com.

"The greatest challenge for the clinical operations function is to coordinate and manage global programs. Each of the multiple parts, multiple support staff, site networks, as well as clinical technology vendors, needs to be managed efficiently to contain costs, manage data, and interpret data in real time to ensure that timely, informed decisions can be made.

Five to 10 years ago, the ICH project encouraged ways that companies could embrace and leverage global capabilities to support processes and requirements of the FDA and other regulatory bodies. At the time, studies were localized, handled by in-house staff, or a full-service company, and were managed within given time zone restrictions. Much has changed since then. Currently, and certainly in the foreseeable future, clinical operations personnel must assemble and manage globally distributed teams with local representation managing national and/or regional regulations and requirements while reporting into a central command or project managers.

More than ever, this global structure will continue to spur the need for clinical technologies to ensure that quality and compliance is being maintained at the site level, and that monitoring activity is based on need rather than scheduled visits. The monitors' roles at sites will take on one of compliance and oversight, as more teams shift to formal internal teams to review and query data, which will maximize the monitor's time on site. Overall, these clinical technologies will take on the role of global command centers to provide the needed support for sponsors, ensuring high standards of quality, as well as end-to-end visibility in real-time for greater study control and management."

KAREN MASSAND is Managing Director, Strategic Advisory at Skila, Morris Plains, N.J., a provider of knowledge-driven management solutions for the pharma industry. For more information, visit skila.com.

"The clinical operations group's primary role is to ensure that internal expectations for clinical studies are met regarding deliverables, milestones, and budgets. But the most challenging part of the job by far is managing communication across functions and alliances, which have become more complex with increased regulatory pressure. With so many stakeholders involved, there are contingent decision processes affected by changes in everything from launch sequence to labeling. A single touch-point solution that houses all trial management metrics so that financial, trial status, and other key measures are tracked is essential to allow clinical-trial teams to easily monitor trials and quickly report any issues.

Ultimately, the transparency provided by strong performance measurement saves millions of dollars for the company and accelerates product launches. It also prevents much of the media noise questioning the legitimacy of clinical-trial disclosures and 'who knew what when,' thus improving public confidence in the company and industry."

DR. JAYE THOMPSON
INVENTIV CLINICAL SOLUTIONS

▶ The core clinical staff is focusing on senior project management and the more flexible staff is taking on responsibilities that can be outsourced.

DR. MICHAEL BUTLER
APTUIT

▶ Contract organizations are playing a much larger role in the development of drug candidates and advancing those candidates into the clinic.

the use of EDC and formats such as CDISC allows for a more seamless transmission of data and information and a better quality of the data that are compiled.

GORDON. KING PHARMACEUTICALS. Using electronic data collection methods is a way of getting more accurate, real-time data from the patient and the site. This also allows for the sponsoring organization to be aware of the data and the study as it is conducted.

Key Performance Indicators

The one thing that hasn't changed and has become more important than ever is the need for accurate metrics and favorable ROI.

DOYLE. KFORCE. Metrics are always critical and will become more so as we focus on rising R&D costs, negative press regarding recent safety issues, the increase in prescription drug costs, and mounting FDA regulatory oversight. If we focus on the process of running clinical trials and apply lean operational metrics to improving efficiencies, we can greatly improve safety, which is always the primary focus, and simultaneously better manage R&D costs and improve cycle times. Anytime we improve efficiencies we improve profitability. Metrics, especially lead indicators, and the ability to analyze and respond to those will greatly improve the reactions of front-line teams that are currently juggling gut instincts that are predominantly based on lagging indicators. If someone told me that analyzing a better way to work would help save lives by making a drug available more quickly and safely — I don't think I'd care if they called it "improving cycle time" or "operational excellence" — I'd find all the ways to improve processes.

EVANS. ESSENTIAL GROUP. Metrics are vital to program success. Project managers, with project teams, have to identify leading and lagging indicators and then project or forecast program outcomes. It is no longer enough to report what happened last week, and then think there is visibility into the future. Projections, including rolling averages, means, trends, and gap analyses are necessary to predict outcomes and make adjustments as quickly as possible.

THOMPSON. INVENTIV CLINICAL. Chasing the wrong metrics can rob companies of efficiencies and can ultimately mislead management and distract them from key project objectives. Metrics such as data quality, enrollment rates, and regulatory status are key measures in the management of clinical operations. For example, the ability to measure site performance at the click of a button is key to ensuring ROI is maximized for each site. Too often, efforts are spent on sites that have historically poor quality or enrollment, which leads to very low ROI at the site level. The ability to identify and select the best sites, set realistic expectations, and track performance against expectation allows an ongoing assessment of ROI. Additionally, having risk mitigation plans in place allows pharmaceutical sponsors and their partners to derive the highest ROI.

BUTLER. APTUIT. In drug development and clinical operations, metrics are vital not only to determine the success of an individual project but also to improve overall processes. Metrics are essential in defining the scope of a project, ensuring that the project is progressing within the proper timeframe, and capturing the type of data sponsors want to collect. Solutions and standards in measuring metrics and ROI are not found in a new technology or computer program, but rather can be seen in the evolving relationship between an innovator company and contract organizations. The industry has always recognized the necessary relationship between a pharmaceutical company and contract organizations, but now there is also the realization that those relationships are not merely a product of capacity issues but rather are driven by collaborative motives. Contract research organizations are playing a much larger role in the development of drug candidates and advancing those candidates into the clinic, and similarly, pharmaceutical and biotechnology companies are looking to contract organizations to step outside the role of simply managing manufacturing and clinical trial-operations to leverage scientific expertise as a way to positively impact the companies' overall portfolios and pipelines.

WAIFE. WAIFE & ASSOCIATES. Of course metrics and ROI are very different from each other. Focusing on only a few metrics can be useful to operational guidance, motivation, and evaluation. The trick is choosing the right ones and getting everyone to know them, own them, and learn from them — which is very rarely done. ROI is a completely different

matter and usually misunderstood. The primary barrier to useful ROI discussions is that virtually no biopharma company accurately understands its current development operational costs, so that a "return" on a "change" cannot be compared with anything meaningfully, because the denominator is unknown. With some research and thoughtful analysis, however, this understanding can be achieved.

GORDON. KING PHARMACEUTICALS. From the pharmaceutical perspective, we cannot overemphasize the importance of metrics in the clinical operations realm. Clinical trials are extremely expensive to initiate, from protocol development through patient enrollment and trial completion. In addition, pharmaceutical companies are facing continued challenges from regulatory agencies to meet ever-changing guidelines and protocols. All available data to measure time and costs to complete each step of the drug-development process are vital to identifying process improvements that can ultimately reduce costs for sponsors. In the future, I expect that companies will examine each step in the clinical operations process to demonstrate more efficient ways of conducting a trial — for example, determining better methods of patient enrollment or more efficient means for closing the database. Ultimately, time and cost-savings in the clinical-trial process will have a positive impact on ROI. ✦

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