BY DENISE MYSHKO

New Directions for *Clinical Directors*

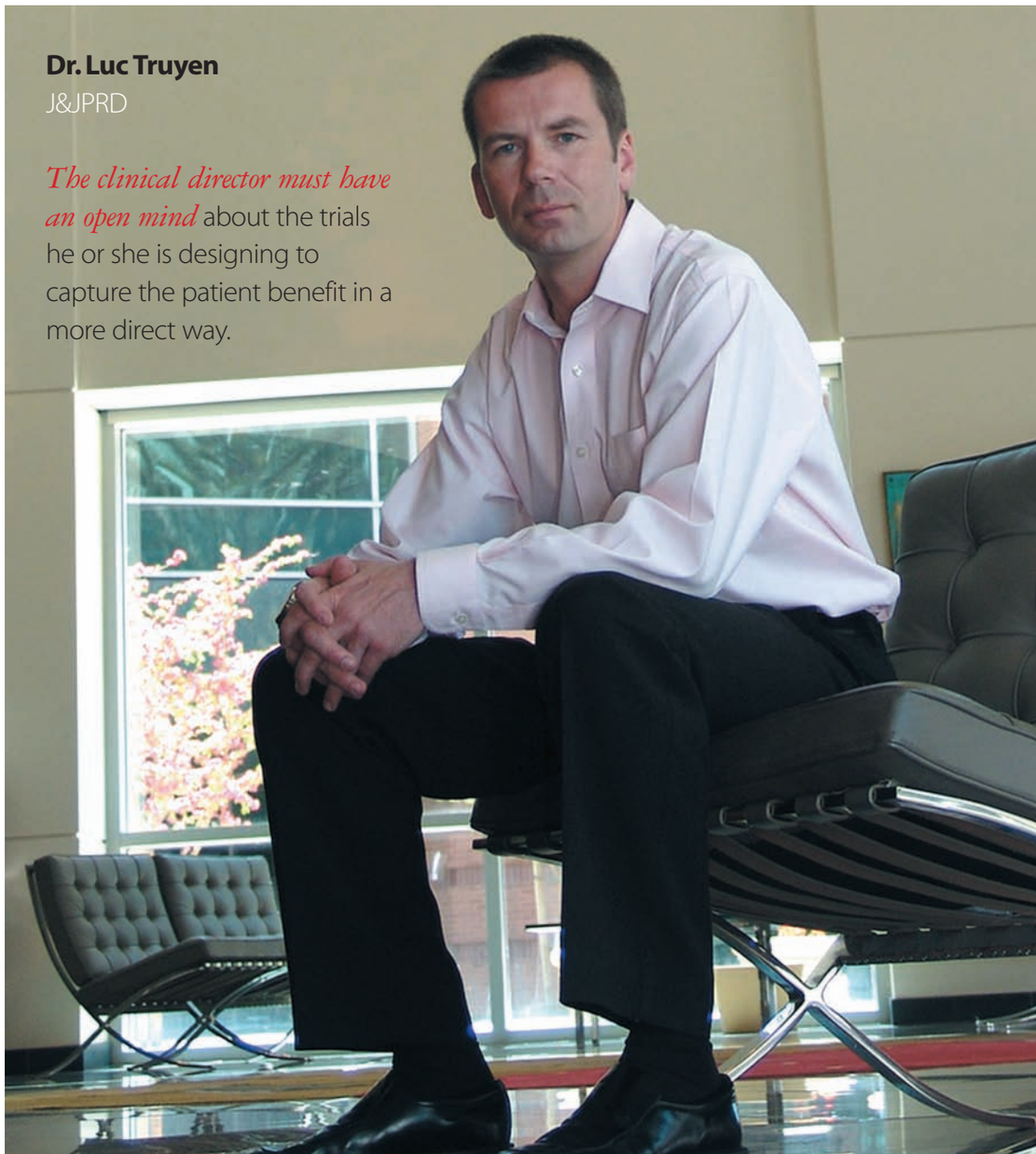
As drug development continues to become global and more complex, ***the clinical director's role is changing as well.***

The function of the clinical director has broadened from a purely medical and scientific advisory role to being the clinical leader responsible for the design and delivery of global clinical development programs. As a result, the clinical director needs to be more vertically integrated and aware of issues related to safety, new technologies, and a faster pace of development.

A Changing Role

A changing regulatory environment, advancing technologies, and increased public scrutiny have resulted in the need for the clinical director to have a broader business scope.

RAK. ASTRAZENECA. The role of the clinical director has broadened from a purely medical and scientific advisory role to serving as the single clinical leader responsible for the design and delivery of clinical development programs globally. This includes providing clinical input to the overall management of the global portfolio. Because strategy and operational delivery are inextricably linked, the clinical director must consider outsourcing and partnering realities that have evolved significantly over the past few years. These new realities make it essential to develop and nurture external relationships to improve clinical-development programs.

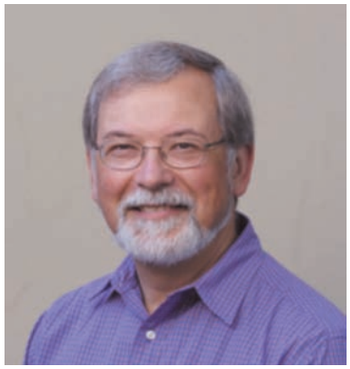


Dr. Luc Truyen
J&JPRD

The clinical director must have an open mind about the trials he or she is designing to capture the patient benefit in a more direct way.

Dr. Carolyn Sidor
EntreMed

The role of clinical directors is going to become more specialized like everything else. They will have their niche and they will be specialized by therapeutic area or by compound, and there's going to be a need for these individuals to be more highly trained.



Dr. Ihor Rak, AstraZeneca

Because strategy and operational delivery are inextricably linked, *the clinical director must consider outsourcing and partnering realities that have evolved significantly over the past few years.*

TRUYEN. J&JPRD. The core role of the clinical director, which is to develop medicines that are safe and add value, hasn't changed at all. What has changed, of course, is the environment in which we have to carry out that mission, with increased regulatory oversight but also public scrutiny of what we do. As such, clinical directors need to be more vertically integrated in the clinical process to manage changing clinical metrics. This means addressing outcomes; patient reported outcomes will become a bigger part of how we measure effect. Therefore clinical directors need to have a more open mind about how trials are designed to be able to capture patient benefits in a more direct way.

SIDOR. ENTREMED. When I became a clinical director in the late 1990s, there was a very well-defined review process for the initiation of trials. Today, this process has become more complicated. In addition to IRBs, we have multiple committees who review protocols. They usually are composed of ethicists, as well as individuals who are well-versed in the therapeutic areas. The process of getting a trial up and running is much lengthier than it was four, five, or six years ago. Costs have gone up, which is inevitable, and the use of global trials is increasing. Now, more and more earlier development is global.

HAVERTY. SCHERING-PLOUGH. Today, clinical directors have to be more nimble. There are internal factors that affect a program, such as having to amend a protocol. But there are also external factors. Another company may come up with a unique design or they may combine two classes of drugs in a therapy area. We read about this in press releases, and we have to adjust our programs accordingly. This didn't happen as fast 10 years ago.

SIDOR. ENTREMED. Today, clinical directors have many more balls to juggle, and they need to have a much broader knowledge base. Clin-

Thought Leaders

RICK FULLER. Executive VP of Research and Development, Aerovance Inc., Berkeley, Calif.; Aerovance is a privately held biopharmaceutical company exclusively focused on developing and commercializing breakthrough medicines for asthma, cystic fibrosis, chronic obstructive pulmonary disease, and eczema. For more information, visit aerovance.com.

MATHIEU M. GHADANFAR, M.D., FAHA, FESC. Global Brand, Medical Director for Tekturna, Novartis Pharma AG, Basel, Switzerland; Novartis is a world leader in offering medicines to protect health, cure disease, and improve well being. For more information, visit novartis.com.

THOMAS HAVERTY, M.D. Group VP, Global Clinical Research, Schering-Plough Corp., Kenilworth, N.J.; Schering-Plough is a global science-based healthcare company with leading prescription, consumer, and animal-health products. For more information, visit schering-plough.com.

MICHAEL POOLE, M.D. VP, Neuroscience Clinical Research and Development, Wyeth Research & Development, Collegeville, Pa.; Wyeth is one of the world's largest research-driven pharmaceutical and healthcare products companies. For more information, visit wyeth.com.

IHOR RAK, M.D. VP, Clinical Neuroscience Therapy Area, AstraZeneca US, Wilmington, Del.; AstraZeneca is an international healthcare business engaged in the research, development, manufacture, and marketing of prescription pharmaceuticals and the supply of healthcare services. For more information, visit astrazeneca-us.com.

CAROLYN F. SIDOR, M.D. VP and Chief Medical Officer, EntreMed Inc., Rockville, Md.; EntreMed is a clinical-stage pharmaceutical company developing therapeutics for the treatment of cancer and inflammatory diseases. For more information, visit entremed.com.

LUC TRUYEN, M.D., PH.D. VP, Clinical R&D, Johnson & Johnson Pharmaceutical Research and Development LLC (J&JPRD), Raritan, N.J.; J&JPRD is part of the Johnson & Johnson family of companies and focuses on hematology, oncology, infectious disease, obesity and metabolic disorders, neurology and psychiatry, pain, and women's health. For more information, visit jnjpharmarnd.com.

Sound Bites from the Field — LEADING TRENDS

PHARMAVOICE ASKED SUPPLIERS TO THE PHARMACEUTICAL INDUSTRY TO ADDRESS THE LEADING TRENDS IMPACTING CLINICAL DIRECTORS TODAY.

KAREN CARROLL is Senior Director, Project Management, Clinical Data Operations, Octagon Research Solutions Inc., Wayne, Pa., a process-centric solutions provider that offers a suite of regulatory, clinical, process, and IT solutions to the life-sciences industry. For more information, visit octagonsolutions.com.

"Accelerating project timelines or establishing unrealistic project timelines is becoming the norm rather than the occasional request. As a result, the clinical department is constantly struggling to make it happen. Key components of the project can become rate-limiting factors to efficient project start up. In addition, the benefit of using thought leaders is at risk because they are frequently at institutions that have their own contract and budget reviews and approval processes or have long queues for IRB approvals.

Compounding all of this are the normal issues that arise. If the project is not appropriately managed throughout its entire life cycle, project teams can become disenchanted and clinical-trial sites frustrated by the constant sponsor demands. Eventually, this can impact the quality of the study and the trial sites' interest in the current project, as well as jeopardize their interest in doing future work with the sponsor or CRO."

MARY-LYNN FULTON, MPH, is Director, Clinical Operations, Clinical Research Services, at Parexel, Waltham, Mass., which offers a range of services to assist the pharmaceutical, biotech, and medical-device industries in bringing new products to market. For more information, visit parexel.com.

"A key trend currently impacting clinical development is the evolution of the traditional clinical research associate (CRA) position into a site manager role. The focus of site monitoring has transformed from auditing functions to one in which the site manager takes complete ownership for the performance of the site, often across multiple studies occurring simultaneously or in succession.

The industry's move toward the increased use of paperless technologies, such as electronic data capture (EDC), has helped to enable this evolution by reducing the time CRAs spend at sites on source document verification, query resolution, regulatory document review, and drug accountability. This gives them more time to train site personnel, work with sites to develop customized patient recruitment plans, proactively identify and manage potential quality and compliance issues, and set action plans in place. This shift should result in both greater efficiency and higher data quality."

SARA GAMBRILL is Senior Editor of Thomson CenterWatch, Boston, a publishing and information services company. For more information, visit centerwatch.com.

"The ability to conduct clinical research in emerging regions — such as China, India, and Russia — that offer rapid patient-enrollment timelines and quality data has created a truly global market for clinical trials. In Russia alone, between 2004 and 2006, the number of patients participating in global clinical trials has tripled.

The trend has been driven by the dual pressures of increased patient requirements for Phase III trials and the quest for speed to market. While emerging countries share some similar and desirable characteristics, each has unique advantages and challenges that clinical directors must be cognizant of to get the best of what each has to contribute."

SARAH POWELL is Executive Director, Regulatory Strategies, Liquent, Thomson Scientific, Philadelphia, a provider of essential electronic workflow solutions to business and professional customers. For more information, visit scientific.thomson.com.

"Companies are expanding the use of innovative technologies to reduce costs of clinical trials and ensure better patient safety. An emerging industry standard for the electronic exchange and submission of clinical information with regulatory bodies, known as the Study Data Tabulation Model (SDTM), and other CDISC-driven standards are factors impacting clinical development decisions. A recent PhRMA-Gartner-CDISC study indicated that use of these standards can result in substantial reductions in cost and time related to data capture, data clean up, and data analysis and reporting. Communications and data exchange among sponsors, CROs, regulatory authorities, and other third parties are much faster, accurate, and cost-effective when these standards and processes are employed."

STUART YOUNG is Global Head, Clinical Monitoring Operations, at Chiltern International Inc., Carlsbad, Calif., a global contract research organization with extensive experience running and staffing international Phase I to Phase IV clinical trials across a broad therapeutic range. For more information, visit chiltern.com.

"The CRO sector is concentrating efforts on partnering and supporting clinical directors' abilities to control competing product development imperatives to drive down time and costs, to improve study start-up efficiency, and to maximize patient recruitment by widening the geographical spread of clinical studies. Additional trends include the use of electronic technologies to capture data produced by both the investigator site and patients. This is leading to greater flexibility within CROs as the profile of services change to support these technologies, for example, electronic data capture training at the site. In addition to the technological trends, the one key element is further globalization reflected in increased use of sites in Central and Eastern Europe, Asia, and Latin America.

Finally, there is a much greater focus on post-registration strategies, which translates into more specialized activities such as safety and registry studies."

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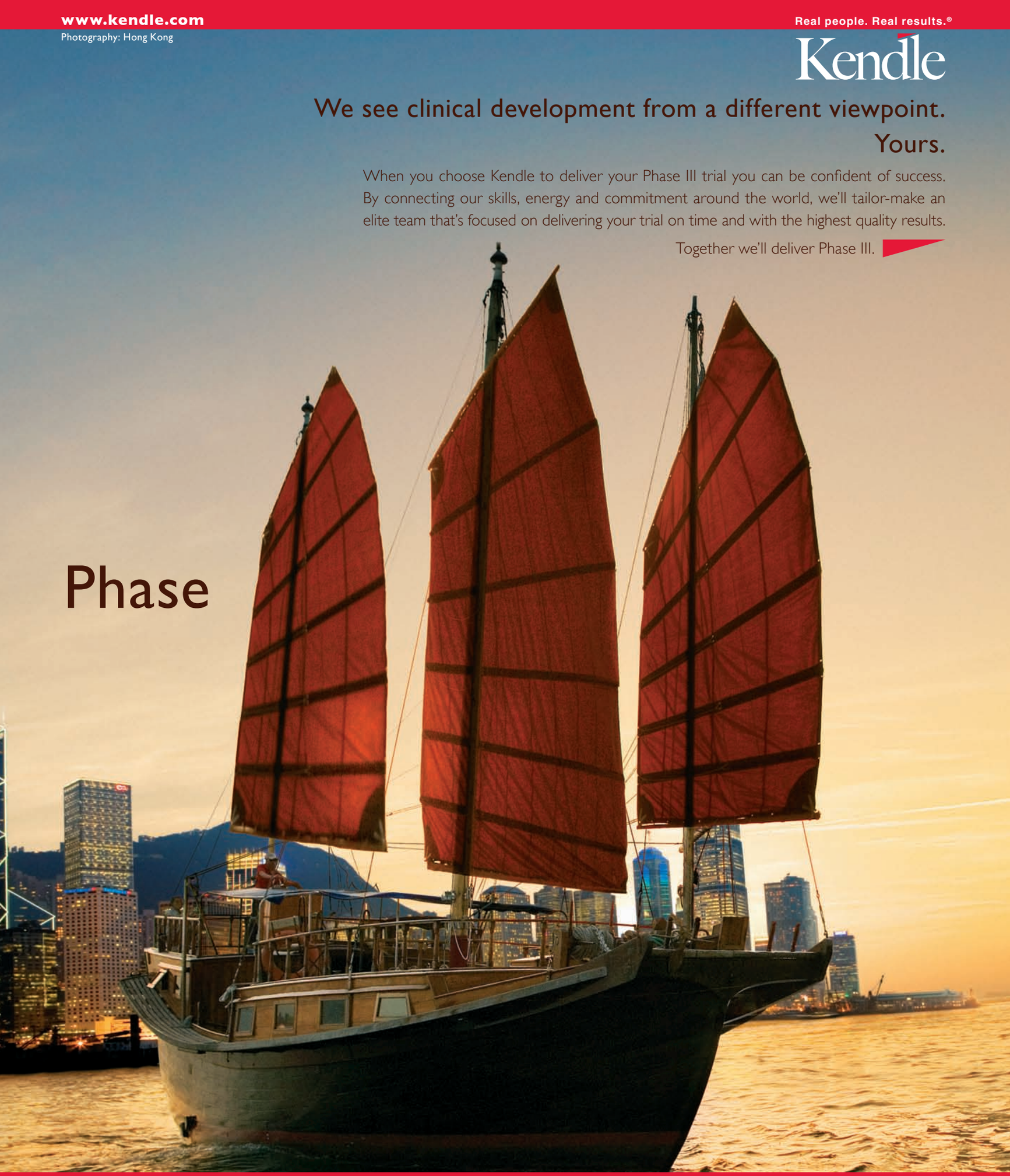

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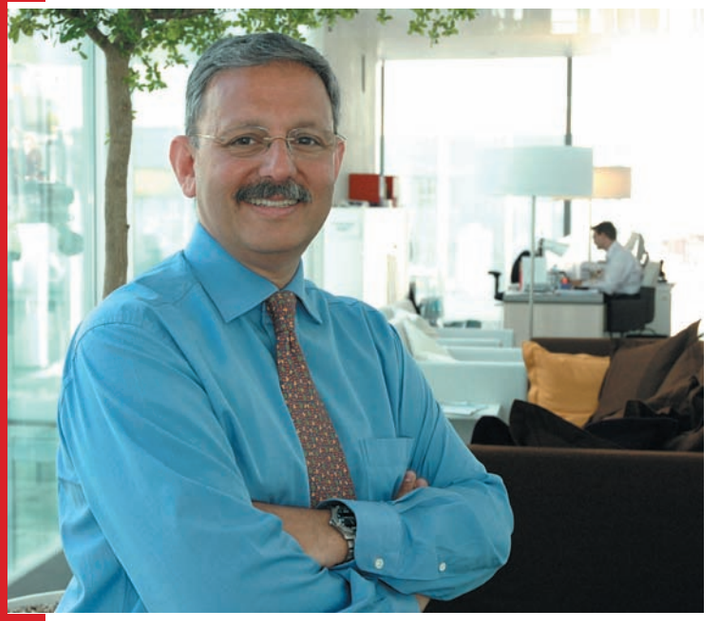

Dr. Mathieu Ghadanfar, Novartis Pharma

The clinical director role has changed — *and we will see continued change* — because the industry is facing a very complex and constantly changing regulatory environment.

Rick Fuller, Aerovance

Clinical-trial operations are now separated from the strategy behind trial protocol design. *Gone are the days when people try to manage both.*

ical directors can't just specialize in one area and they can't do things the same way they were done before and expect processes to work going forward. They have to be flexible and they have to be able to multitask. Clinical directors have to be well organized, and they have to be current, because when regulations change, which they do on a weekly basis, they have to be able to react accordingly. It's not only about managing the studies; it's also managing the regulations around the studies.

FULLER. AEROVANCE. There has been a separation of functions for the operation of the clinical trial, in terms of regulated activities and strategic decisions around the actual trial protocol design. The qualifications needed for the different functions are very different.

GHADANFAR. NOVARTIS. In many organizations, clinical development and medical affairs are separate; medical affairs is viewed as supporting the commercial side and is not always connected to clinical development. In Novartis, the role combines clinical development and medical affairs, and this is not a traditional approach. The clinical director becomes the leader for global clinical strategy and the scientific advisor for clinical development. We are seeing a continued change in this role because the industry is facing a very complex and constantly changing regulatory environment. Dossiers have become bigger and bigger, especially worldwide dossiers that have to comply with multiple country regulatory requirements. Because of the cumbersome nature of the process, it's critical to have a person in place who has complete technical and regulatory knowledge to lead the entire program.

FULLER. AEROVANCE. It is now commonplace for companies to outsource clinical trials, which means there is a need for someone to manage external relationships. When I started in the industry, none of the big pharma companies outsourced their trials to any extent. Nowadays, all pharma companies outsource a percentage of their trials and small companies, such as ours, outsource all clinical operations.

Meeting the Demands of a Changing Role

Globalization, a focus on safety, and a faster pace of development are likely to lead to increased demands on clinical directors.

SIDOR. ENTREMED. Clinical directors are going to become specialists, just like everything else. They will have a niche by therapeutic area or by compound. There's going to be a need to make sure these individuals are highly trained. Clinical directors will hold M.D., Ph.D., and equivalent degrees.

RAK. ASTRAZENECA. As the demand for safer and more differentiated medicines developed cost-effectively increases, leaders in these roles must be adept at understanding, communicating, and balancing patient benefit and risk throughout the development and marketing of medicines. They also must seek innovative delivery models and ensure that studies deliver good, clear-cut clinical decisions. Projects must always progress in the best interests of patients and without potential risk to healthy volunteers, even in the earliest clinical studies. There also is growing emphasis on being more externally visible to bring deeper customer insights into clinical work.

HAVERTY. SCHERING-PLOUGH. In the next five years, we are going to be expanding into new territories, namely China, India, Central and Eastern Europe, Latin America. These areas are not in the ICH trio, so we're going to have to understand what it takes to develop drugs in these countries.

POOLE. WYETH. Out of necessity, the clinical director role will become more international in scope. We'll need to become more familiar with both investigative sites and capabilities in regions of the world that haven't been tapped before, such Latin America and Asia. There is a push to globalize development for two reasons: to have products that will be safe and successful around the world and to find new patient populations for studies. We need to be much more capable with our interactions in the international arena than we were 10 years ago.

RAK. ASTRAZENECA. Globalization is a significant trend that is creating shifting market dynamics. The growing importance of Asia and other emerging markets will require a deeper understanding of customer needs and medical practices that affect clinical development, as well as regulatory, ethical, and operational delivery realities. More broadly speaking, in today's complex world, we must integrate globalization, cross-cultural teamwork, cost pressures, and an increased focus on patient safety with both newly approved medicines and investigational drugs being administered to healthy volunteer subjects in research studies.

HAVERTY. SCHERING-PLOUGH. For me, what's changed most has been the pace and acceleration of development, and much of this can be attributed to globalization and the increased

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Sound Bites from the Field — BEST PRACTICES

PHARMAVOICE ASKED SUPPLIERS TO THE PHARMACEUTICAL INDUSTRY TO ADDRESS BEST PRACTICES FOR MANAGING TRIALS AND IMPROVING THE PHARMA/SUPPLIER PARTNERSHIP.

JONATHAN ANDRUS is VP, Data Management and Regulatory Operations, at Phoenix Data Systems Inc., King of Prussia, Pa., a provider of electronic data capture services for the pharmaceutical industry. For more information, visit phoenixdatasystems.net.

"The current surge in EDC and e-clinical technology use is dramatically affecting traditional clinical-trial roles. While these tools have numerous benefits, sponsors should not expect them to completely replace people and experience. Applying technology to old processes is a recipe for no real change or even disaster. Implementing technology without the proper management and controls will be similarly less than satisfying.

The best results are most consistently achieved when sponsors devote adequate resources to manage — within whatever solution they choose — issues that span process change, training, support, satisfaction, and essential communication between all participants. Sponsors should create a function that looks at all aspects of the clinical-trial continuum and determine how to best leverage existing personnel. This role also works with technology and service partners to set realistic expectations, reduce risk, and get the best possible results for every trial."

GERRY HEPBURN is Senior Director, Clinical Packaging and Logistics, at Aptuit Inc., Greenwich, Conn., which focuses on streamlining and supporting the drug-development process for biotechnology and pharmaceutical innovators. For more information, visit aptuit.com.

"As drug development continues to become global and more complex, suppliers need to provide a service as well as employ highly experienced consultants who can manage the process effectively and efficiently. These scientific advisors can be imbedded within a sponsor company, acting independently to recommend the best solutions, even if from competitors. By acting in the sponsor's best interest, suppliers go beyond temporary customer/supplier collaboration to create long-lasting working relationships that benefit both parties. Joint development activities, such as cost-reduction plans, pipeline review, and reciprocal key performance indicator (KPI) measurement can strengthen these relationships.

Drug development is currently disjointed by multitudes of conflicting IT systems. Suppliers need to link the steps by building IT systems that enable end-to-end project management and test data across the entire continuum. Transparent IT gives sponsors real-time project status and paperless review and approval, which streamlines the process and minimizes human error."

EDUARDO F. JAHN is Associate Director of Operations of Criterium Inc., Saratoga Springs, N.Y., a full-service, global CRO that offers a mix of high-quality clinical research services, real-time data acquisition, and personalized communication processes to manage a clinical trial from initial planning to approval. For more information, visit criteriuminc.com.

"As a project manager, the key is paying proper attention to the planning portions of the project. The rule of 20/80 applies: increase the planning process by 20% and gain an 80% growth in productivity. The requirements of sponsors have to be defined and clarified. This allows for the customization for a specific project.

Some of the major components of a well-planned study include: prioritizing deliverables to keep a team tightly focused, maintaining realism in planning short- and long-term goals, keeping milestones close together and relevant, communicating regularly about plans and progress, delegating tasks and empowerment of people wherever possible, and managing vendor activities. A properly planned study includes measurement and reporting of results at established intervals as they come in, along with consistent communication to sponsors about changes and productivity. Finally, conducting a structured lessons-learned feedback program during and after the project points to aspects of procedures that can be modified for the future."

RON KERSHNER is Senior VP of Clinical Operations at inVentiv Clinical Solutions, Malvern, Pa., a business segment of best-of-class providers in clinical staffing, clinical operations, biostatistics, and data-management solutions. For more information, visit inventivhealth.com/clinical.

"It is important for sponsors to weigh the cost-benefit of information gathered in any clinical trial. Sponsors often tend to err on the conservative side when designing the protocol and CRF and can end up collecting information that is not related to the primary endpoints of the study. Information that is critical to the study objectives set forth in the protocol should be reported, tabulated, and analyzed. But storing ancillary information for a separate study or analysis can save the time and cost incurred to clean, tabulate, and present such information in appendices to the study report.

Additionally, when the safety footprint of a study drug has been relatively well defined, Phase II and III studies should focus on determining potential biological toxicities by using generic normal ranges or focus the safety analyses on various risk-factor analyses relative to key biologic endpoints typically independent of normal ranges."

HUGH LEVAUX, PH.D., is VP of Product Strategy at Medidata Solutions Worldwide, New York, a global provider of electronic clinical data capture, management, and reporting solutions. For more information, visit mdsol.com.

"Partnership arrangements require partners. It behooves both suppliers and sponsors to seek strategic outsourcing agreements that span multiple trials or cover entire therapeutic areas. Strategic agreements work best when both parties share some risk in the success or the failure of a given program.

It is unreasonable to expect suppliers to share in the cost of a failed compound; after all, the suppliers do not directly reap the benefits of a successful compound. By the same token, it is reasonable to expect that the suppliers do accept incentives based on target milestones.

For technology suppliers, enterprise arrangements are the necessary starting point. Sponsors commit to a certain number of studies over a given period of time and the technology supplier oftentimes agrees to a schedule of improvements, functionality upgrades, and so on, embedded as contractual obligations. Study burn rates are a function of how efficiently the software can be learned, used, and rolled into production.

Accelerating the burn rate and adoption of the software for all trials serves as a powerful incentive for the technology vendor to listen to the requests by the sponsors, CROs, and users and to provide agile and efficient software."

BRUCE SMITH is Executive Director, Clinical Operations, at United BioSource Corp., Bethesda, Md., a global pharmaceutical services organization that helps emerging and established life-sciences companies develop and commercialize medical products, with a particular focus on generating real-world data. For more information, visit unitedbiosource.com.

"Defining and supporting a successful transition from contract to operational teams is the single most important way to ensure the success of clinical studies. While the partnership can be seen primarily from a business perspective — for example, as a contract to provide goods and services — this misses a key element: building solid relationships.

To this end, there are two formal, face-to-face meetings that need to take place. First, a meeting with key players from both contracting and operations teams will lead to a shared understanding about the scope of services and timelines. Processes, terminology, and outcomes should be delineated so that everyone has the same lexicon about expectations.

Next, during a face-to-face project kickoff meeting — with extended teams from both sides — this set of expectations should be communicated, which then builds the understanding, trust, and openness necessary for long-term success. At this point, a dialogue can start about options, helping to avoid problems before the work begins."

KEVIN VERNAREC is VP of Clinical Operations at Icon Clinical Research Inc., North Wales, Pa., a global provider of outsourced development services to the pharmaceutical, biotechnology, and medical-device industries. For more information, visit iconclinical.com.

"In today's current drug-development environment, delays in the project timelines resulting from the sponsor or the supplier often have a significant impact on the quality of the partnership arrangement between sponsors and their suppliers. This ultimately affects the sponsor's satisfaction of work performed by the supplier.

It is my opinion that maintaining an open, honest, and timely communication channel between sponsors and their suppliers greatly improves the partnership arrangement, which results in better teamwork, quality, and overall satisfaction with sponsor companies. When partnerships are not mutual, suppliers do not believe they can openly engage the sponsor with issues affecting their timelines and deliverables.

Too often, adversarial relationships can develop because of poor communications and a failure to relay timely information on both ends, resulting in significant delays and cost overruns on clinical projects."

use of information technology. The pace of development is quickening, and information is delivered faster.

GHADANFAR. NOVARTIS. Another trend involves clinical safety and benefit/risk based on the recent drug withdrawals by the FDA and other regulatory agencies because of safety issues, as well as the halting of major clinical programs. Over the last five years, clinical directors have become more focused on looking at the safety and benefit risk of their daily activities and their clinical studies. There is an immense focus on safety by regulatory agencies, and the FDA is implementing additional assessment of the safety of drugs 18 months after introduction. Clinical directors need to always scrutinize data, improve evaluation systems to detect potential signals earlier, and manage risk effectively.

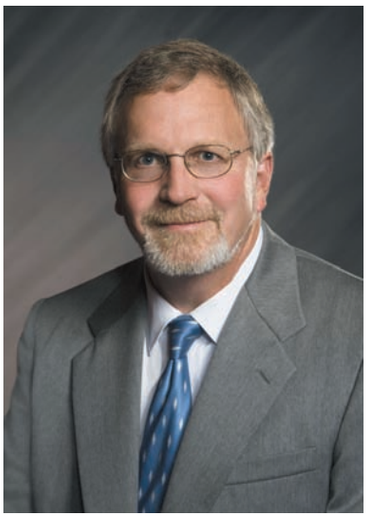
POOLE. WYETH. There is more emphasis on the early phase of development, that is the identification of the appropriate dose and to determine whether the compound works. The biggest difficulty we have in the clinical realm is getting to successful Phase II experiments, and that means not only determining whether the compound works but identifying the correct dose.

Best Practices

Our industry experts discussed best practices for managing clinical trials, working with suppliers, and leading their teams.

RAK. ASTRAZENECA. Management of clinical studies will be improved if we design them better and more simply, with earlier input from all relevant stakeholders — patients, regulators, payers, clinical investigators, and academic thought leaders. Obtaining the best input early also will minimize changes later in the form of amendments. Ascertaining every partner's expectations and contributions to the clinical research enterprise early on and having these understood and accepted will help ensure an efficient delivery of data that result in progressing medicines of true value to patients and society.

GHADANFAR. NOVARTIS. It is important to share and apply knowledge from other development programs. There is a lot of learning that can be applied by speaking to other development brand leaders, and it's always good to apply the knowledge as a way to avoid mistakes. At Novartis, we have a concept of international clinical/project teams, which encompass a cross-functional representation of project



Dr. Thomas Haverty
Schering-Plough

For me, what has changed most is the pace and acceleration of development, and that involves globalization and increased use of information technology.

Dr. Michael Poole, Wyeth

The clinical director role will, out of necessity, have a more international scope. Clinical directors will need to become more familiar with both investigative sites and capabilities in other regions of the world.

management, regulatory, safety, country representation, and so forth. As a clinical brand leader, clinical directors sit on those international teams and drive the global medical strategy. They also can leverage the experience of the Development Project Board to receive additional experience and expertise because these teams cannot operate in isolation.

HAVERTY. SCHERING-PLOUGH. A best practice is to be knowledgeable about the regulations and understand what it takes for programs to succeed in regions around the globe. One really has to understand the standard of care in all countries. It is important to conduct the studies against the background of the standard of care. What helps us work in this globalized environment is to adopt and integrate new information technologies tools and practices.

POOLE. WYETH. There is much more reliance on electronic data capture, the use of standardized instruments for analyzing and interpreting data, and understanding the requirements of doing international clinical trials. This means clinical directors have to understand both the culture and the scientific capability of the investigators in countries around the world.

SIDOR. ENTREMED. We like the team approach to both the design and conduct of the study, which includes the clinical site, the statistician, the regulatory affairs department, translational research, and so on. We have built our organization on a matrix design and team approaches. We find this leads to the best product. This also gets buy-in from all the various groups that control a component of the process that would be important to the effective design of a study.

HAVERTY. SCHERING-PLOUGH. In a globalized environment, it's important to understand different cultures and what's important to patients and how clinical-trial systems work. One has to become good at managing through international teleconferences using Web-based tools.

TRUYEN. J&JPRD. We have to make sure that whatever we do is in line with good clinical practices and asks a valid scientific question. For me, research ethics have always been very important. This means asking: Can I defend why I'm doing this study now in this subject.

SIDOR. ENTREMED. Because we outsource many of the activities of the clinical trials, we like to involve CROs as part of the team. It's easy to assume these are fee-for-service organizations, but if they understand the science and participate at an equal level, we find that they become an effective resource. A best practice for working with CROs involves effective communications.

FULLER. AEROVANCE. A best practice is to view the CRO as part of the internal team, not as an external source. At Aerovance, for example, we have the CRO join our project team discussions, usually on the phone. We prefer having them as part of the team rather than having an "us-versus-them" type of relationship.

TRUYEN. J&JPRD. A best practice is to be very clear about what the end goal is and get consensus around it. This means more than simply having a protocol and running with it, but having the partner understand why we are undertaking the study, why there is a certain timeline, and why we need to be diligent about execution to meet the mission. Shared goal setting with outside partners is core to every contract that we enter into.

GHADANFAR. NOVARTIS. At Novartis, every clinical trial is assigned a clinical-trial head, and he or she leads the clinical-trial team(s) and is accountable and responsible for all aspects of the study. He or she is the one who works across all the CROs, as well as with all the other line functions and identifies which countries to target. A best practice is keeping regular contact, which means the clinical-trial team meets regularly and frequently, and we go over the progress of all aspects of the study, including operations, and identify early on what the hurdles are, and how we can address issues that impact the timeline and recruitment concerns. We resolve issues by proactively reaching out to our trial committee or advisors. This will ensure timely delivery of high-quality analysis of clinical-trial data, which enables strategic decisions within the clinical program.

POOLE. WYETH. As much as possible, clinical directors should allow suppliers to use their methods and their own standards to achieve the outlined objectives without imposing a lot of external requirements. Outsource partners should be involved early in the plan and not just the protocol, they need to understand what is to be accomplished, and then there should be incentive-based performance targets that can be worked toward.

RAK. ASTRAZENECA. I focus on personally demonstrating good leadership of the programs that I am accountable to deliver. I rely on articulating a vision of the potential medicine and how clinical development teamwork can achieve the end goal. They need clear objectives and they need to know how to exceed them. I also coach my teams continuously on their leadership responsibilities, focusing on how things are done rather than simply that they are done, and addressing noncollaborative behaviors promptly and openly. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.