BY TAREN GROM

WHO, WHAT, WHERE, WHEN, & HOW

CLINICAL SERVICE PROVIDER AND SPONSOR PARTNERSHIPS

Dr. Patrick Nef FAUST PHARMACEUTICALS

CROs need to share risk with the client, otherwise there are no reasons for the provider to be on time, efficient, and committed.

The cost of drug development has soared in the past 10 years, which is why pharmaceutical and biotechnology companies are looking for new and smarter ways to conduct clinical research.

Therefore, the question is not whether to outsource critical research functions, but determining who, what, where, when, and how for improved efficiencies and faster results.

THOUGHT LEADERS

KEVIN BISHOP. Chief Operating Officer, Global Operations, ClinPhone Inc., Princeton, N.J.; ClinPhone provides a range of services that are driven by the integration of Internet and telephone-based technologies, enabling process improvement for pharmaceutical and biotech sponsors as well as CRO partners. For more information, visit clinphone.com.

LARRY A. BLANKSTEIN, PH.D. Senior Director, Clinical Research, Genzyme Corp., Cambridge, Mass.; Genzyme is a biotechnology company focused on rare inherited disorders, kidney disease, orthopedics, cancer, transplant and immune diseases, and diagnostic testing. For more information, visit genzyme.com.

JOHN CLINE. CEO, etrials Worldwide Inc., Morrisville, N.C.; etrials offers an e-clinical platform for integrating clinical data from a variety of sources and allowing secure, real-time reporting of results through Web-based interfaces, as well as helping companies seeking to migrate from paper-based to electronic methods. For more information, visit etrials.com.

SYLVA H. COLLINS, PH.D. VP, Global Head, Advanced Clinical Systems, Novartis Pharmaceuticals Corp., East Hanover, N.J.; Novartis has core businesses in pharmaceuticals, consumer health, generics, eye care, and animal health. For more information, visit novartis.com. (The opinions expressed in this Forum are those of Dr. Collins and not necessarily those of Novartis.)

HOLLY O. COULTER. Executive Director, Development Operations, Purdue Pharma L.P., Stamford, Conn.; Purdue Pharma and its independent associated companies in the United States are known for their pioneering research on a principal cause of human suffering: persistent pain. For more information, visit purduepharma.com.

PETER A. DIBIASO. Director, Clinical Trial Recruitment Services, Pfizer Global Research and Development, New York; Pfizer discovers, develops, manufactures, and markets leading prescription medicines for humans and animals and many of the world's best-known consumer brands. For more information, visit pfizer.com.

CHRISTOPHER GALLEN, PH.D., M.D. President and CEO, Neuromed Technologies Inc., Vancouver, British Columbia; Neuromed is

WHO?

The optimal provider/client relationship is based on many factors, including communications, trust, and a strategic partnership.

GODWIN. We proactively enter into a relationship with the approach that it will be a strategic partnership. The terms of enterprise are important to both parties to mutually benefit from the relationship and to conduct business in a positive best-practice fashion with reciprocity. Concordance is a strategy that sets the expectations and tenor for the alliance and for future work. At the inception of the relationship due diligence is done to assure compatibility. Throughout the partnership, communication is the key component to success. A good communications roadmap will keep the team aware of opportunities and any mitigating factors.

HERRING. The optimal provider/client relationship is one of strategic collaboration. To build and grow productive partnerships requires that both parties — the service provider and the sponsor — commit to and live up to five values that build and continually strengthen this type of relationship. First, both sides need to aspire to a good that is greater than the individual or group. While not easy to achieve, especially in science-based environments, this is critical; and it is up to the leaders of each company not only to demand, but also to model the behavior. Second, both the provider and sponsor need to remain committed to the brutal truth, no matter how much it hurts. To achieve higher aspirations, everyone has to be grounded in a culture where the unvarnished truth is welcomed, recognized, and rewarded. We need to focus on what is right, not who is right. The third value is to treat team members as "insiders." This eliminates the "us vs. them" mentality that damages the relationship between the client and provider. Insider status for all team members builds trust, gets the best ideas to the table, and keeps everyone focused on the ultimate goal. Fourth is communications. Open, honest communications are essential. A good starting point is to establish an executive oversight committee with senior representatives from both sides. The committee fosters communication, provides perspective, applies resources appropriately, and monitors progress. Through its actions and example, the committee also sets expectations for the full team. And fifth, trust is earned through performance. This means flawless delivery and operational excellence by the joint client-provider team.

BLANKSTEIN. Within Genzyme, there are some trials that are outsourced totally and there are others that have pieces outsourced. The decision as to what to outsource and when to outsource depends upon what resources we have available internally to work on that project. Then, in terms of selecting vendors, in many cases we choose vendors that we have worked with in the past. It really comes down to relationships.

MURPHY. There is no one-size-fits-all approach to good provider/client relationships. The characteristics of an optimal relationship between a vendor and a small biotech company may be very different from the characteristics of an optimal relationship between a vendor and a large multinational pharma company. It is critical for a provider to understand the unique needs of each client and structure the relationship to support those needs.

GALLEN. The optimal provider/client relationship requires the client to be clear on its needs and expectations and the provider to have the ability and proven track record to meet those expectations. An optimal provider has sufficient knowledge to add value to the relevant program and a level of integrity that allows it to operate effectively with only limited supervision, providing an acceptable product or outcome. The provider must operate transparently, bringing to the surface problems and helping devise and execute solutions expeditiously.

SERODY. I agree with the premise that relationships have to become more strategic between the clinical-services providers and sponsors. But how do we get there? The best

a private biopharmaceutical company committed to developing the next generation of chronic pain drugs. For more information, visit neuromedtech.com.

RICHARD GLIKLICH, M.D. President and CEO, Outcome, Cambridge, Mass.; Outcome is a provider of Web-based solutions for quality initiatives and post-approval programs. For more information, visit outcome.com.

SHAREN GODWIN. VP, Strategic Development, PharmaTech Solutions Inc., Wilmington, N.C.; PharmaTech Solutions is an established, full-service patient recruitment company providing innovative services enabling profitable clinical research. For more information, visit pharmatechsolutions.com.

AMES GROSS. President and Founder, Pacific Bridge Medical, Bethesda, Md.; Pacific Bridge Medical helps American medical companies with business development, marketing strategy, and regulatory issues in Asia. For more information, visit pacificbridgemedical.com.

JOSEPH L. HERRING. President and CEO, Covance Inc., Princeton, N.J.; Covance is one of the world's largest drug-development services companies with operations in 17 countries. For more information, visit covance.com.

SIMON S. HIGGINBOTHAM. VP and Chief Marketing Officer, Kendle, Cincinnati; Kendle is a global CRO delivering innovative and robust clinical-development solutions to help the world's biopharmaceutical companies maximize product life cycles and grow market share. For more information, visit kendle.com.

JOHN HUDAK. President and Founder, Criterium Inc., Saratoga Springs, N.Y.; Criterium is a global contract research organization that offers a unique mix of high-quality innovative clinical-research services and communication processes to manage a trial from initial planning to approval, on time and on budget. For more information, visit criteriuminc.com.

DAVID KUBERSKY. Managing Director, Life Sciences Division, Ness Technologies, Hackensack, N.J.; Ness Technologies is a global provider of end-to-end IT services and solutions designed to help clients improve competitiveness and efficiency. For more information, visit ness.com.

TIMOTHY S. LACROIX. Senior VP, Fleishman-Hillard Inc., Clinical Trials Division, Durham, N.C.; The Fleishman-Hillard Clinical Trials Division is an international communications-based organization that ▶

Holly Coulter PURDUE PHARMA

First and foremost, it is essential for the sponsor to be clear about the deliverables involved in each project. These include timing, quality, communications, process, and cost.

Adam Serody DIMENSIONAL HEALTHCARE INC.

During the last few years, there's been an increase in Phase IIIb, Phase IV, and community-based trials, and there are several reasons for this. **The current landscape includes a decrease in NMEs and the resulting NDAs. At the same time, our regulatory environment is changing as a result of recent product recalls and safety concerns.**

working relationships result from "a good-fit" scenario. If the clinical-service provider is a good fit for the sponsor then it becomes easier to move down a common path in which there are strategic advantages for both parties. In my experience, a good fit is dependent on several factors. One important factor is therapeutic alignment. If the sponsor focus is specialty-based, for example on oncology, and the CRO doesn't align therapeutically, then there is a misalignment of talent when it comes to providing services. A mismatch of skill sets can impact the study. That being said, there are many therapeutic areas in which experienced project management teams can be very competent even if the therapeutic area is not a core competency for the clinical-service provider. The sponsor team must decide which is more important for their specific trial. Size and organizational structure are other important factors. Very large pharmaceutical companies tend to be a more labor-intensive fit for mid-size and smaller CROs. These larger organizations have a different outsourcing philosophy and seem to seek out the larger global CROs. Midsize CROs align very nicely with much of industry, including biotech and small- and midsize pharma. This is due in part to similar organizational management structures that provide for more efficient communication and decision making, positively impacting timelines. Then there's outsourcing strategy. It's important that this be a complementary aspect between sponsor and service provider. In the last several years, CROs have had to become more flexible to meet sponsors' needs. Bundled services are no longer the best match for most sponsors. Sponsors are so varied in what they have in house, CROs need to be able to respond to individual services and rely

THOUGHT LEADERS

provides clinical services to keep programs and clinical trials on track, such as multinational centralized patient recruitment and retention services. For more information, visit fleishmanclinical.com.

VINCENT LAGROTTERIA. Senior VP, Sales, Marketing, and Strategic Alliances, Medifacts International, Rockville, Md.; Medifacts is dedicated to providing quality clinical-trial services to pharmaceutical, biotech, and medical-device companies that are developing cardiovascular drugs and products. For more information, visit medifacts.com.

MARK LEVINE. Director of Business Development, Averion Inc., Framingham, Mass.; Averion provides clinical-trials support for biotech, pharmaceutical, and medical-device companies in the design, execution, and reporting of clinical trials. For more information, visit averioninc.com.

BRUCE MALOFF, PH.D. VP, Business Development, Services, Invitrogen Corp., Carlsbad, Calif.; Invitrogen provides products and services that support academic and government research institutions and pharma and biotech companies worldwide in their efforts to improve the human condition. For more information, visit invitrogen.com.

ZEV MUNK, M.D. President and CEO, Pharm-Olam International Ltd., Houston; Pharm-Olam International is a multinational contract research organization offering a wide range of comprehensive, clinical-research services to the pharmaceutical, biotechnology, and medical-device industries. For more information, visit pharm-olam.com.

JIM MURPHY. VP, Business Development and Marketing, ICTI-Interactive Clinical Technologies Inc., Yardley, Pa.; ICTI specializes in the implementation of interactive trial-management solutions that enable clients to expedite clinical-trial development on a global scale. For more information, visit icti-global.com.

PROFESSOR PATRICK NEF. CEO, Faust Pharmaceuticals SA, Strasbourg, France; Faust Pharmaceuticals is a biotech company with a drug-discovery strategy that focuses on large unmet medical needs and small molecules: neurodegeneration, neurotransmitter modulation, G-protein coupled receptors, and allosteric modulators. For more information, visit faustpharma.com.

BETSY NORRIS. VP, Business Development, Edgewater Technology Inc., Wakefield, Mass.; Edgewater is a strategic consulting firm that specializes in providing technical consulting, custom software development, and systems integration services. For more information, visit edgewater.com.

KIM OLIVER. Director of Clinical Operations, Kforce Clinical Research, Tampa, Fla.; Kforce Clinical Research, a division of Kforce Inc., provides a full range of clinical-research

Peter DiBiaso

PFIZER GLOBAL RESEARCH AND DEVELOPMENT

No matter what size the company is, **it's critical that it has the ability to retain the institutional knowledge and lessons learned.**

Yota Palli BIOCOR

The sponsor and the CRO need to form a partnership, a team, where everybody's strengths and expertise are integrated to best support the defined objectives.

less on the traditional full-service model and the associated loaded costs.

HUDAK. The optimal sponsor/provider relationship is one where the needs are clearly stated, by the client and the provider, and both deliver on those requirements. Because delivery of services takes place over a long period, the relationship requires that both parties are willing to meet to reinforce the needs or effect a change as circumstances dictate. And it comes down to the people — their experience, their training, and their personality. These are the individuals with whom the client interacts.

OLIVER. One of the most important factors in developing an optimal relationship is for the provider to have similar corporate values to the sponsor. Another key success factor is to develop a joint-ownership mentality. Rather than "throwing the project over the fence" with the expectation that the provider will deliver without sponsor involvement, there should be co-ownership, clearly defined expectations, and shared problem solving. The end result will be improved outcomes without the "us vs. them" mindset. When problems do occur, the solution will be much easier to identify and implement if the sponsor and provider work together to take responsibility for the problem and the solution. Providers should also be willing to make their performance very visible so the sponsor is always aware of what is taking place. This can be accomplished through regular face-to-face meetings as well as through such tools as performance metrics, quarterly business reviews, and frequent progress reports. Finally, and most importantly, providers should have a proven track record of recruiting, hiring, training, and retaining the clinical talent needed for the full life of the project. The bottom line is that great people equal great results.

DIBIASO. From Pfizer's perspective, the company has the size, scope, and scale to be able to support most core requirements with internal resources; I appreciate that many other companies might not have this same luxury. Irrespective of a company's size, it's critical that the organization has the ability to retain the institutional knowledge and lessons learned during the conduct of the study. From my perspective in subject recruitment, the relationships that we develop with our investigator sites and the experiences we gain from enrollment planning, tracking, and performance evaluation are criti-

monitoring services for Phases I-IV clinical trials, including outsourced regional monitoring; clinical project management; regional program development; and direct placement and staff augmentation services across a wide range of functions in support of clinical research. For more information, visit kforce.com.

YOTA PALLI. VP, Business Development, BioCor, Yardley, Pa.; BioCor is a benchmark clinical research organization that specializes in clinical-data services and consulting to support Phase I through Phase IV programs from clinical plan design to defense of global regulatory submissions. For more information, visit biocor.com.

RICHARD D. PURCELL. President, ClinPro Inc., Bound Brook, N.J.; ClinPro is an independent, full-service clinical research organization offering veteran clinical researchers with expertise in a variety of therapeutic areas. For more information, visit clinpro.com.

SHERRY REUTER, B.S.N., M.S. Senior Clinical Project Leader, Alexion Pharmaceuticals Inc., Cheshire, Conn.; Alexion is engaged in the discovery and development of therapeutic products aimed at treating patients with a wide array of severe disease states, including cardiovascular and autoimmune disorders, inflammation, and cancer. For more information, visit alexionpharmaceuticals.com. Ms. Reuter also is an adjunct professor of clinical research at George Washington University.

ADAM SERODY. VP of Clinical Solutions, Dimensional HealthCare Inc., Cedar Knolls, N.J.; Dimensional HealthCare provides late-phase medical research to the pharmaceutical and medical-device industries. For more information, visit dhcare.com.

BILL TAAFFE. President and CEO, ICON Clinical Research - U.S., North Wales, Pa.; ICON Clinical Research is a full-service clinical research organization providing a comprehensive range of clinical services in Phase I-IV clinical trials to the pharmaceutical, biotechnology, and device industries. For more information, visit iconclinical.com.

MANDI B. WALTERS. VP, Business Development, Metropolitan Research Associates, New York; MRA is a full-service CRO specializing in project management and monitoring, drug safety, and clinical staffing. For more information, visit metropolitanresearch.com.

RICHARD A. ZAKOUR, PH.D. General Manager, Senior VP, BioServices, McKesson Specialty, Rockville, Md.; McKesson BioServices provides cost-effective solutions using a focused process for clinical supplies and biological specimen management outsourcing, covering preclinical through Phase IV studies, working closely with the U.S. government, universities, CROs, and pharmaceutical and biotechnology companies throughout the clinical-trial process. For more information, visit mckessonbio.com.

GROWTH AREAS IN CLINICAL-SERVICE OUTSOURCING

PharmaVOICE asked experts from the leading clinical-trial service providers which outsourcing areas are expected to experience growth in the next two to three years.

Enterprisewide Technologies

MITCHELL BAYER IS VP, STRATEGIC ALLIANCES, MEDIDATA SOLUTIONS INC., NEW YORK, WHICH DEVELOPS FLEXIBLE, ENTERPRISE-CLASS WORKFLOW AND WEB-BASED TECHNOLOGY TO ASSIST GLOBAL LIFE-SCIENCES AND RESEARCH ORGANIZATIONS TO ACCELERATE THE PROCESS OF BRINGING LIFE-ENHANCING TREATMENTS TO MARKET. FOR MORE INFORMATION, VISIT MDSOL.COM.

A growing number of leading pharmaceutical and medical-device companies have chosen Medidata's technology for use on an enterprisewide basis. This reflects a growing trend to standardize companywide on a single technology and reap the improved economy and effectiveness of common processes and streamlined analytics. At the same time, we are also seeing increasing demand from CROs interested in implementing EDC technology through partnership models that provide a more cost-effective way to move forward. We think the EDC firms that are able to offer partner programs to satisfy the unique demands of services organizations will enjoy this emerging trend and continue to realize significant adoption by CROs of EDC expertise in the next two to three years.

We all know that it is not optimal for a sponsor to pick a partner right before a study is about to launch or for CROs to pick their partners only after they win a study.

Unsurprisingly, though, this happens all the time. Successful partnerships require a much more thorough understanding of the organizations involved than can easily be understood late stage, when a study launch looms. Picking the right partner, assembling cross-functional teams, adjusting SOPs, involving stakeholders in the crafting of a plan lined with both tactical and strategic events, are all things to do early to ensure success and help define the true potential of the partnership.

cal to our future successes, as well as continued improvement. We risk losing much of this direct knowledge if we hand over these key responsibilities to an external provider. When we evaluate the elements that will be outsourced, we ensure that there is a predefined reporting mechanism or feedback loop to ensure Pfizer retains the core site relationships. There needs to be clear and concise objectives for what would be expected as a result of the partnership — mutual trust, open communication, and equitable compensation.

COULTER. First and foremost, it is essential for the sponsor to be clear about the deliverables involved in each project. These include timing, quality, communications, process, and cost. Without clearly defined expectations and a communication plan that both client and provider can commit to, there is a low likelihood that the relationship will be successful. Ongoing communications are particularly important for enabling emerging issues to be identified quickly and mutually satisfying solutions to be developed.

NEF. CROs need to share risk with the client, otherwise there are no reasons for the provider to be on time, efficient, and committed. The client needs to make sure that the CROs are reimbursed based on pre-agreed milestones and that they have someone in house who is aware of the common pitfalls to prevent them.

COLLINS. There is no question that the cost of drug development has soared in the past 10 years. Like all businesses, pharma companies look for ways to achieve their objectives at lower cost. I believe, however, that posing the question as "not whether … but who, what, where, when, and how" carries some hidden suppositions. These suppositions are basic. The first supposition is that CROs can provide a given service at lower cost. The second is that a CRO can provide quality equal or better to that possible by other means. To address the components of the question, "who, what, where, when, how," a company must first know, with some precision, its internal costs. A CRO cannot carry out a task at lower cost just because it is a CRO. To provide a service at lower cost, the CRO has to have some economic advantage. If it is merely doing the same thing as big pharma, not only will its costs not be lower, but big pharma will be burdened with the additional costs of a CRO's marketing expenses and need for legitimate profit. Before deciding to use a CRO, a sponsor company must first not only understand its own costs but also understand how these costs will change if part of its process is outsourced. Any honest calculation of internal costs will show that fully half the cost is allocated to corporate overhead. Typically, CRO contracts are unburdened by internal corporate overhead allocations. This is an accounting fiction. Unless a sponsor somehow reduces its fixed overhead when outsourcing, overhead allocations are merely transferred to some other department. Conversely, cost accountants could legitimately allocate, conservatively, 30% to 50% of the overhead to CRO contracts. Were this to occur, the financial advantage of CROs would vanish. Irrespective of the reputation of the CRO, it is the sponsor alone who bears the burden of ensuring the quality of the service provided. No responsible pharmaceutical company can fail to devote significant resources to overseeing its CROs. At best, the cost of oversight is 10% to 20% of the nominal cost of the contract.

WALTERS. Every provider/client relationship strives to achieve a true partnership. For that to

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Cardiac Safety Core Laboratory Services

ROBERT BROWN IS SENIOR VP, OUTSOURCING PARTNERSHIPS, AT ERESEARCH TECHNOLOGY INC., BRIDGEWATER, N.J., WHICH IS FOCUSED ON PROVIDING TECHNOLOGY AND SERVICES TO ENABLE THE DIGITAL COLLECTION, INTERPRETATION, AND DISTRIBUTION OF CARDIAC SAFETY AND CLINICAL DATA TO ACCELERATE CLINICAL DEVELOPMENT MORE EFFICIENTLY. FOR MORE INFORMATION, VISIT ERT.COM.

The outsourcing of cardiac safety core laboratory services, primarily digital 12-lead ECGs, continues to be an area of great growth. Our global business is driven by the needs of our sponsors in Phases I-IV to reduce overall costs and reduce data variability through a centralized model of ECG data analysis and by our sponsors' desires to follow the guidance of international regulatory authorities in the conduct of specialized Thorough QT Studies, which require core lab support with demonstrated high-quality experience and scientific know-how, validated technologies and processes, capacity, regulatory compliance, and best value.

There's no better time than early in Phase I to partner with an ECG core lab provider to support a specific compound. Interpretation of an integrated summary of safety is facilitated and there is greater confidence in the accuracy of the interpretation of the results when the ISS is comprised of a single ECG data evaluation methodology and consistent reporting backed by documented regulatory compliance. Partnering can scale up from support of a single protocol to the integrated support of all protocols in a program, multiple programs within a therapeutic group, or multiple therapeutic groups across a sponsor organization.

Dr. Sylva Collins NOVARTIS

A CRO cannot carry out a task at lower cost just because it is a CRO. To provide a service at lower cost, the CRO has to have some economic advantage.

be attained, a few key elements must exist: there should be a clear understanding of each party's responsibilities outlined in a task ownership matrix; measurable goals and objectives should be established with common metrics used to measure progress; senior management buy-in and support on each side should exist and executives should be available for open, honest discussion; a communications and rapid resolution process should be established, as well as a periodic review; and teams from both the sponsor and provider should be respectful of each other's opinions and insights. Ultimately, it's a CRO's consultative strengths that make it an invaluable partner.

BISHOP. Both the provider and the client have to enter the relationship with the clear intent of acting as true partners. There has to be a clear understanding of the client's expectations as well as the provider's human, technological, and geographical resources and processes. Over and above the project management and other activities relating to project delivery, there also needs to be a commitment for decision makers on both sides to work together to steer and manage the relationship between the organizations. This steering committee can look at issues such as future project planning, service enhancements, technology development, issue escalation, and resolution and agreement on longer-term pricing structures.

LAGROTTERIA. Both the CRO and the sponsor need to view each other as respected and trusted partners. In the situations that have had positive outcomes, it was because the project teams from both sides became one project team working toward a single objective. The second criteria for an optimal relationship lies in the ability to meet or exceed expectations on both sides. The CRO and the sponsor have the responsibility to make sure that communications are direct and honest. When a sponsor selects a vendor of choice to carry out its research, it is giving a tremendous amount of faith and trust to that provider. This is a huge responsibility. Sponsors start the relationship hoping that all goes well "this time" with a CRO so they can refer more business to the provider. Trust and integrity are earned and never presumed. As hard as it is to build trust in a relationship, it can be destroyed in a heartbeat. When words and actions are not met or when expectations are not managed, the relationship becomes dented. People stop sharing what is really going on because there is a loss of faith in the relationship. This is when the communication becomes challenged, and it is so hard to build back the trust and integrity. As a result of this disconnect, the sponsor decides it will choose another CRO for its next project. The provider loses a good reference and any repeat business.

LEVINE. A relationship should be based on open communication, trust, mutual respect, and integrity. The provider must have the relevant experience and expertise to support the sponsor in the given indication. There has to be a compatible approach and an ability to be flexible and accommodating. Through the course of a study and/or program, unforeseen issues and events can and usually do arise. By collaborating effectively, the sponsor and provider can adjust accordingly for a successful and mutually rewarding outcome.

CLINE. Trust and communication are essential to a positive working relationship. It is the vendor's job to earn that trust, and it is the client's job to give it once earned. Similarly, it is both party's responsibility to facilitate the smooth flow of information. After that, it is important that the vendors make it easy for the clients to do business with them, which can be much more difficult than it sounds. The entire provider organization must be optimized, the communication must be flawless, and the solutions the vendor provides must be effortless for the client to implement. It really takes a total commitment from the provider to simplify the evaluation, purchase, and deployment of solutions. This is especially true in the clinical-trial industry where technology is just a tool researchers use to do their real jobs.

GLIKLICH. Provider/client relationships should be symbiotic and nonduplicative. Providers should allow clients to choose which aspects of the Phase IV study or registry to do themselves and which to outsource. Software solutions should enable all parties to function in an integrated manner toward a common goal.

PALLI. It is very important to clearly define the

GROWTH AREAS IN CLINICAL-SERVICE OUTSOURCING

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Simon Higginbotham KENDLE

Based on a thorough review of the market, we are seeing **encouraging signs that the outsourcing of clinical trials to CROs will only increase.**

Dr. Christopher Gallen

NEUROMED TECHNOLOGIES

Given recruitment difficulties in an already saturated North American and Western European market, **there is clearly room for growth in trial-management services in India, China, South Asia, and Latin America.**

objectives up front so that each team member has a solid understanding of what he or she is expected to contribute and when. The timelines can be aggressive, but they need to be realistic so that quality standards are not compromised. Both sides must be flexible to adjust according to changes in the schedule. The sponsor and the CRO need to form a partnership, a team, where everybody's strengths and expertise are integrated to best support the defined objectives. Like all partnerships, communication, flexibility, and well-defined expectations are the keys to an optimal provider/client relationship.

HIGGINBOTHAM. An optimal relationship is one where we're involved early at a strategic level and, as a result, are able to add expertise and value to the maximum benefit of the customer. It's best when the biopharmaceutical company views us as a partner, sharing pipeline information so we can plan resources accordingly and work together to establish mutually agreed-on approaches for conducting the study and measuring the success of our relationship. Successful CROs recognize they are service organizations that sell a promise.

KUBERSKY. The optimal relationship is one of transparency. The sooner interactions can move away from the classic buyer/seller, the more ground can be covered more effectively. The large part of initial discussions should be more about education than transactions. The relationship should also be based on a "trusted advisor" model. In our business area, which is mostly focused on the information technology aspects of clinical trials, there are a great number of generalists trying to enter the market. But not all outsourcing providers are equal, especially in the areas of validated and regulated applications. We have found that deep business domain expertise is critical to getting an offshoring and outsourcing relationship started in the right direction.

ZAKOUR. I believe that there are three criteria that need to be considered. The first is communications, the second is compatibility, and the third is auditing compliance with regulations. With regard to communication, both sides need to know who, what, when, and how. That way there are no gaps, nothing falls between the cracks, and the lines are open. There has to be compatibility and a collaborative type of relationship. Although this is not absolutely required, outsourcing is not a one-way street, and there really needs to be a partnership to attain a win-win situation. Both parties need to have a clear understanding of each other's expectations and have clearly defined responsibilities. The third criterion that's really important is auditing, particularly for the people who are outsourcing. They need to make sure that they are getting the quality that they need in compliance with the regulations.

Qualified Clinical-Research Professionals

SUSAN L. COULTAS IS PRESIDENT OF INFOQUEST CLINICAL NETWORK INC., A TEXAS-BASED CLINICAL SERVICES NETWORK THAT PARTNERS WITH PHARMACEUTICAL, MEDICAL-DEVICE, AND BIOMEDICAL COMPANIES TO PROVIDE INNOVATIVE CLINICAL OPERATIONS SOLUTIONS FOR PHASE I-IV CLINICAL TRIALS. FOR MORE INFORMATION, VISIT INFOQUESTCLINICAL.COM.

As more companies downsize, merge, regionalize, and otherwise restructure their internal workforces, we are providing a wider variety of services through our IQNet Professional Network. Regulatory challenges that have swept through the industry in the past few years have further created an environment that supports the use of highly qualified and specialized clinical-research professionals.

Members of the IQNet Professional Network have an average of 15 years of experience in their field of expertise; therefore, supplying clients with customized services with experienced and dedicated teams will continue to be our primary growth area as companies augment their own resources to optimize their clinical-research programs.

Sharen Godwin PHARMATECH SOLUTIONS

Developing the study strategy together is an efficient manner to promote collective success.

WHAT?

According to experts, the outsourcing arena is primed for growth in all clinical-trial service areas.

HIGGINBOTHAM. Based on a thorough review of the market, we are seeing encouraging signs that outsourcing of clinical trials to CROs will only increase. This growth in outsourcing crosses Phase I-IV clinical development, regulatory affairs, and biometrics services and is being driven by marketplace changes. For example, heightened concerns recently over the safety of approved and widely prescribed Cox-2 drugs have raised calls for more thorough testing and increased long-term safety surveillance. The recent establishment of the Drug Safety Oversight Board within the FDA, the increasing and more rigorous requirements for postmarketing commitments, and the government's continued focus on drug safety are holding pharma to a higher standard than ever before. This is creating a tremendous opportunity for CROs.

HUDAK. All areas of trial services are ripe for growth. The labor-intensive parts, for example the monitoring and data entry, have historically been contracted. But new areas that target those aspects of clinical studies that inhibit study completion, for example patient enrollment or data interpretation, are likely to grow. Sponsors are looking for guaranteed patient enrollment and guaranteed study success. Companies are requiring a menu of clinical-driven services, such as protocol writing, site solicitation, monitoring, data management, statistical services, and report writing, as well as complete clinical-development services, from clinical-development planning to regulatory submissions.

NEF. Flexible, early clinical research organizations have the greatest potential for growth, as they have to be able to run a Phase I and Phase II trial to receive a rapid and efficient set of data. This allows for a "go/no-go" decision for further full clinical development — Phase III. Today, almost all functions can be outsourced. The trick is to balance the budget constraints, the need for speed, and the level of control of the process. The difficulty can be managing a dense network of variable service providers.

BISHOP. We are experiencing significant growth in two areas: the collection of clinical assessment and outcome data directly from subjects participating in clinical trials — electronic patient-recorded outcomes (ePRO) — and the desire of an increasing number of biopharm companies to integrate the processes that we manage more closely with their own or partner CRO desktop applications, such as CTMS, EDC, and drug supply-management systems.

MALOFF. E-clinical and ePRO strategies are currently included in 5% to 10% of clinical studies. The most important expense in a clinical trial is time, and for the other 90% of trials, we are wasting a great deal of it in "the paper

GROWTH AREAS IN CLINICAL-SERVICE OUTSOURCING

PharmaVOICE asked experts from the leading clinical-trial service providers which outsourcing areas are expected to experience growth in the next two to three years.

Project Management

ROBERT DAVIS, PHARM.D., IS CHIEF OPERATIONS OFFICER OF RESEARCHPOINT, AUSTIN, TEXAS, A FULL-SERVICE CRO THAT APPLIES EXPERT CLINICAL DEVELOPMENT STRATEGIES TO THE IMPLEMENTATION OF CREATIVE, YET APPROPRIATE SOLUTIONS. FOR MORE INFORMATION, VISIT RESEARCHPOINT.COM.

We have experienced a large increase in the number of companies requesting proposals to include project management, monitoring, and data management, where we cross-train team members in areas that are traditionally separated. I anticipate the same core services of project management, monitoring, and data management will be in great demand, but with more of an emphasis on electronic data capture. I see monoclonal antibody-based products and medical devices being especially robust areas of growth. The optimal time for partnering is highly dependent on the size, sophistication, and the commitment to partnership of the company doing the outsourcing. Certainly earlier is better, probably best, when there is at least a draft of the development plan or protocol, depending on the scope of services being sought. Being a recognized voice at the table strengthens the partnership and enhances the likelihood of a successful collaboration.

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Central Lab Services

ERIC F. HAYASHI IS PRESIDENT AND CEO OF LABCONNECT LLC, SEATTLE, A CENTRAL LABORATORY SERVICES COMPANY THAT PROVIDES SPECIALIZED CUSTOMER SERVICE, INNOVATIVE DATA MANAGEMENT AND REPORTING SYSTEMS, AND COMPETITIVE PRICING STRUCTURES. FOR MORE INFORMATION, VISIT LABCONNECTLLC.COM.

Our focus in on emerging biopharma, and that's where I envision the greatest growth. Outsourcing success is a derivative of R&D expenditures (projected 10% growth) and the percentage of those dollars outsourced (projected 15% growth). All boats rise as they say, and I believe these macro factors will benefit central labs and all of our outsourcing brethren. Phase I is hot today. This portends robust Phase II+ demand. The companies that will be "hot" tomorrow are those that are investing in their human capital and service philosophy today to take advantage of the next 36 months.

This survey, jointly conducted by PharmaVOICE and the Institute for International Research, sponsor of the 14th Annual CRO Partnership conference, consists of three parts, including: company demographics, outsourcing strategies, and CRO services.

Do you use CROs for conducting clinical trials?

RESPONSE

Yes	72.1%
No	27.9%

How many CROs do you use for your clinical trials?

RESPONSE

1	11%
2 to 5	61%
more than 5	27.8%

What type of CROs do you usually work with? (select all that apply)

RESPONSE

Small	12.9%
Mdsize	32.3%
Large	19.4%
Specialized/Niche	19.4%
Size is not a factor when choosing a CRO	16.1%

When do you usually engage a CRO for your trials?

RESPONSE

Preclinical	10.5%
Phase I	26.3%
Phase II	26.3%
Phase III	15.8%
Other	21.1%

What percentage of your clinical trials do you outsource to CROs?

RESPONSE

100%	
76% to 99%	33.3%
51% to 75%	11.1%
26% to 50%	16.7%
11% to 25%	27.8%
0% to 10%	0%

Who in your organizaton makes clinical-trial outsourcing decisions, assuming VP, director, and management level.

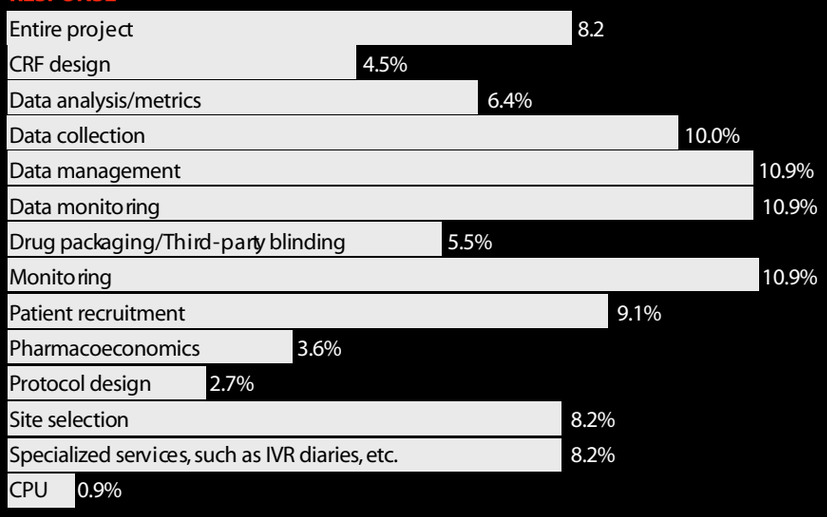
RESPONSE

Clinical affairs	25.0%
Clinical operations	25.0%
Clinical program management	12.5%
Clinical R&D	6.3%
Other	31.3%

CRO Strategy Survey – CRO Services

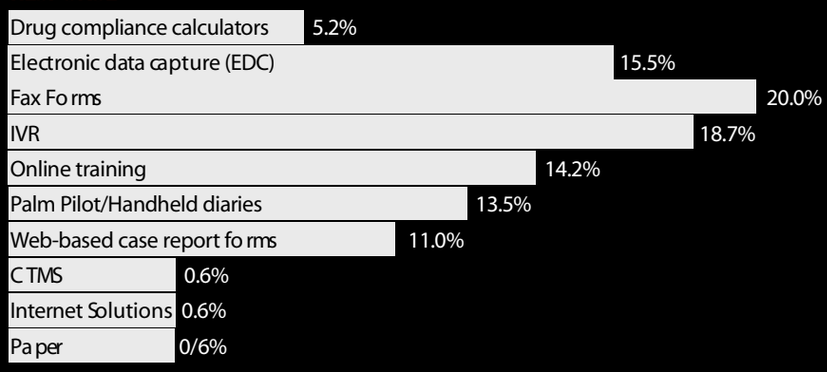
What aspects of your clinical trials do you use a CRO for? (select all that apply)

RESPONSE



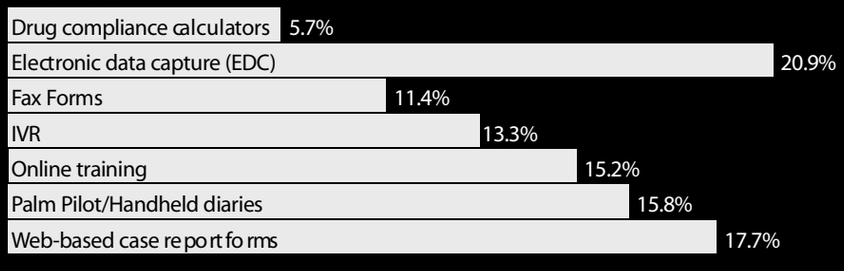
What technologies do you currently use in conducting your trials? (select all that apply)

RESPONSE



What technologies do you plan to use in the next five years?

RESPONSE



Source: PharmaVOICE, Titusville, N.J. For more information, visit pharmavoice.com.
Note: Survey analysis is based on 84 responses from PharmaVOICE readers: company breakdown — 62% pharmaceutical; 10% biotechnology; 8% biopharmaceutical/biology; 7% device, diagnostic, or equipment; 4% service; 2% drug-delivery; 1% generic: and 6% other. The majority of respondents are corporate and marketing managers.

GROWTH AREAS IN CLINICAL-SERVICE OUTSOURCING

PharmaVOICE asked experts from the leading clinical-trial service providers which outsourcing areas are expected to experience growth in the next two to three years.

EDC

FAIZ KERMANI, PH.D., IS A MARKETING EXECUTIVE AT CHILTERN INTERNATIONAL LTD., BERKSHIRE, UNITED KINGDOM, WHICH HAS EXTENSIVE EXPERIENCE RUNNING TRIALS FROM PHASE I TO PHASE IV ACROSS A BROAD THERAPEUTIC RANGE. FOR MORE INFORMATION, VISIT CHILTERN.COM.

With R&D investment at an all-time high, there is increasing pressure on the pharmaceutical industry to boost new drug output. Clinical trials continue to account for an ever-greater portion of R&D spending as companies need to generate high-quality data to convince regulators and clinicians, as well as future users in the general population, that a product is of clinical benefit.

An increasing number of compounds are expected to reach Phase II and III because of the number of compounds that entered Phase I over the last few years. There also is an increasing level of Phase IV research as competition between companies intensifies. All services relating to clinical trials are set to grow.

For example, we expect to experience increased use of EDC. According to current estimates, between 10% and 20% of clinical trials worldwide incorporate the use of an EDC system, and this figure is expected to rise to 50% of trials in the near future. But what will be critical to EDC's future success will be in ensuring that those involved in the trials are being fully trained and supported so that there are no barriers to the use of EDC.

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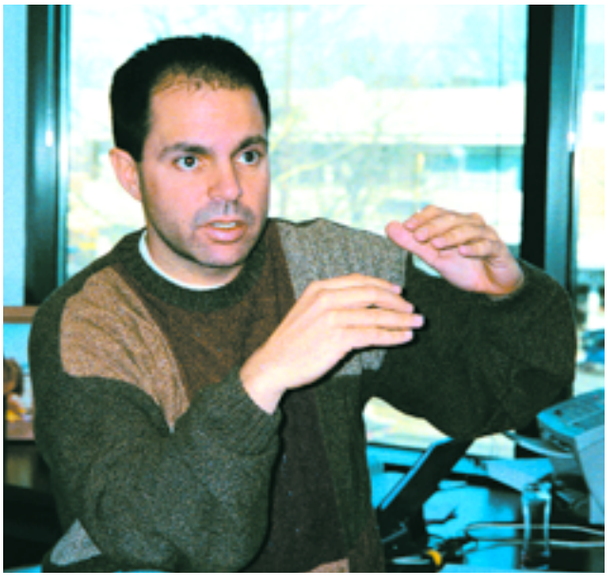
EDC

JAMES LANGFORD IS PRESIDENT OF DATALABS INC., IRVINE, CALIF., A DEVELOPER OF INTERNET-BASED APPLICATIONS FOR CLINICAL DEVELOPMENT THAT HELP THE BIO-PHARMACEUTICAL INDUSTRY ACCELERATE CLINICAL TRIALS WITH PROVEN SOFTWARE FOR STUDY DESIGN, DATA CAPTURE, AND DATA MANAGEMENT. FOR MORE INFORMATION, VISIT DATALABS.COM.

First, I believe that EDC will continue to be a hot industry issue. As clinical trials comprise a significant portion of the time and cost it takes to bring a new drug to market, the ability to conduct clinical trials faster, more efficiently, and with fewer resources is very quickly becoming a critical strategic advantage for success. EDC and related technologies for clinical development offer tremendous potential for cutting costs and speeding much-needed drugs and therapies to market. The EDC industry has grown from $123 million in 2001 to $205 million in 2004, and it will continue to grow as the technology makes a bigger impact on industry costs and efficiency. Adoption will become more rapid as more of the mass market realizes the power of using EDC. More important, however, is the consolidation of disparate paper-based systems and EDC and how those processes will become intertwined.

Despite the growing acceptance of EDC, the rate of adoption will be hindered by the hurdles that come with operational change. Companies are accustomed to the "old" way of paper-based systems and are hesitant to change to the "new" way of EDC systems. To mitigate many of the potential negative effects that come with change, a system that provides a dual solution, and that bridges the old and new ways, is optimal for many companies that are thinking twice about adopting an EDC solution. Adverse event and safety reporting systems and the integration of those systems with EDC technology will be another hot issue.



Vincent Lagrotteria

MEDIFACTS

Both the CRO and the sponsor need to view each other as respected and trusted partners.

chase." E-clinical services will have a significant impact on reducing errors in trials and, with quicker access to cleaner data, will reduce the size of patient populations needed for those trials. Providers that offer integrated e-solutions — IVRS, EDC, CTMS, ePRO, and so on — will experience the greatest potential for growth. At the level of discovery, there has been a very significant shift. Pharma companies continue to drive biotech investments to bolster their pipelines, with more than $50 billion invested during the last two years. Outsourcing discovery to services companies also is gaining traction from both pharma and biotech sponsors for the same reasons that drive outsourcing of development: gaining insights, efficiencies, and speed. The shift will continue and accelerate for those companies that can provide integrated discovery and development solutions.

MURPHY. The use of technology to accelerate the clinical-trial process, reduce costs, and improve data quality is a key area for potential growth. In the past few years, we have observed a significant increase in the adoption of IVRS, EDC, ePRO, and clinical-supplies forecasting technologies.

SERODY. During the last few years, there's been an increase in Phase IIIb, Phase IV, and community-based trials, and there are several reasons for this. The current landscape is experiencing a decrease in NMEs and the resulting NDAs. This has placed more importance on late-phase trials and marketed products. More importantly, the current regulatory environment is changing given the recent product recalls and safety concerns. This is where community-based trials can be very effective. They address the usual care settings in which continued safety, patient-reported outcomes, quality of life, more diverse patient populations, pharmacoeconomic analysis, and risk assessment can be measured.

PURCELL. A company can call itself a CRO or whatever it wants, but we are in the business of providing pharma and biotech companies with data that they can use for their submissions to regulatory agencies for approval and so they can market drugs. The best way to market drugs is with data. The data have to be clean, and they have to be analyzable. The way to get to these clean data packages faster and better is through technology.

GALLEN. I see an increasing proportion of discovery and early-development work occurring in the biotech/small pharma sector for a variety of reasons. Since these companies often work in a much more virtual and under-resourced manner than big pharma, there should be a steady increase both in CRO and central lab trial-management services, as well as more opportunity to provide value-added intellectual and consulting resources for trial biomarker/proof-of-concept design and regulatory services.

OLIVER. Study monitoring, clinical-data management, and safety are probably the three areas with the most potential for growth, largely because studies are increasing in size, complexity, and duration. Another driving factor behind the growth in these services can be traced to safety concerns, which have necessitated more long-term safety data and postmarketing surveillance. That, in turn, increases opportunities for providers that can supply these services, as well as for companies that can train people to fill those positions, because there will be a shortage of experienced clinical professionals as demand continues to increase. There is a real focus now on regionalization and not just for monitoring. We're experiencing an increase in requests from sponsors interested in strategies to regionalize other functions, such as data management and safety. Part of what's driving this trend is that many companies simply don't have space on their campuses to house the escalating number of people they need for these larger, more complex studies. They prefer to hire contract labor to fill resource requirements, rather than outsourcing these critical services. So the challenge is to find a way to apply resources to a project by taking advantage of technology that allows a company to build and manage virtual teams to create a flexible resource pool that doesn't need to be colocated with the sponsor. Another shift is the huge

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EDC

ANNE S. LINDBLAD, PH.D., IS VP OF THE EMMES CORP., ROCKVILLE, MD., A PRIVATELY OWNED CONTRACT RESEARCH ORGANIZATION, ESTABLISHED IN 1977, DEDICATED TO PROVIDING STATISTICAL AND EPIDEMIOLOGICAL EXPERTISE, COMPUTER SYSTEMS DEVELOPMENT, DATA MANAGEMENT, STUDY MONITORING, REGULATORY GUIDANCE, AND OVERALL OPERATIONAL SUPPORT TO CLIENTS ENGAGED IN CLINICAL AND BIOMEDICAL RESEARCH. FOR MORE INFORMATION, VISIT EMMES.COM.

Electronic data capture is an obvious area that is expected to experience growth. Although it is gaining acceptance, it still surprises me how often the industry is reluctant to require this capability in its outsourcing partners. Efficiencies in timeliness of data reporting, improved data quality, and real-time data/study monitoring are obvious advantages. Sponsors must rethink how data will be processed and monitored to take advantage of this technology rather than applying a paper-based mentality to this paradigm.

As we move to incorporating more genomic information into clinical studies, using information technology will become an imperative in the data collection and management process.

Kevin Bishop CLINPHONE

Over and above the project management and other activities relating to project delivery, **there also needs to be a commitment from decision makers on both sides to work together to steer and manage the relationship between the organizations.**

demand for oncology experience. Everyone wants monitors who are highly trained in monitoring oncology studies, but there's a real shortage of those skills. We're finding that clients are getting very specific about the types of technologies monitors know how to use, even down to specific versions of EDC software. Finally, a greater focus is being placed on investigator selection. Sponsor companies often have set lists of investigators they use frequently, but they need new investigators, not involved in competing studies, to maximize patient enrollment. It's a very competitive field, and it's very difficult to find good investigators who can enroll patients. To overcome this, sponsors are increasing their outsourcing of site selection.

GODWIN. Patient recruiting has gained prominence in study value. In the last few years, published research statistics have illustrated the lost revenue in drug and device development because of recruitment challenges. There are two markets in recruitment: outreach and site. Typically, concentration is placed on the outreach market using media advertising to attract patient candidates. A major focus is to integrate the study sites and their efforts more into the recruitment efforts. The sites are the point of care and responsible for executing strategy. Therefore, we are continually assessing how to make their jobs easier, incorporate feedback, measure outreach investments, and performance-tune the strategy.

COULTER. Monitoring, clinical-data management, and study management continue to be the primary areas of outsourcing, given their transactional nature. Companies also are delving into new technologies such as e-diaries and, to a lesser extent although consistently, EDC technologies. The biggest area for growth that we have experienced is in patient-recruitment services.

WALTERS. With the trend of functional service provider models cycling around again, outsourcing individual tasks associated with a trial has been on the rise. In the last few years, outsourcing clinical-research monitoring as a task-based function has increased, allowing not just CROs but clinical-staffing firms as well to bid on projects. As far as growth potential, I think the area of drug safety is best positioned. With the recent focus from the FDA on drug safety, it will be an area of concern for most clients. In the past, clients were hesitant to outsource drug safety because of proprietary and security concerns. But in the past few years, technology and provider approaches have advanced to a level of sophistication that has given clients a greater comfort level in this area.

MUNK. Regulatory activities and pharmacovigilance have become outsourced more over the past few years. This is because of the numerous biotech and device companies that have recently been established. The global nature of many trials has complicated these functions. These companies find it cost-effective and less of a drain on their manpower to outsource these functions as well as various other components of their clinical-development programs.

COLLINS. The questions posed by this Forum can be fairly answered only when a sponsor has a realistic and precise understanding of its own internal costs. Hiring a CRO would be attractive if the CRO total cost, fairly reckoned, is substantially less than the internal cost. This condition will exist if the sponsor is a small company that cannot sustain large fixed costs or if the sponsor is a large company whose procedures have gotten so out of control that it can no longer accurately calculate its internal costs. In this case, the CRO is providing a type of cost insurance — if not any real financial advantage — by signing a fixed-price contract. Needless to say, this conclusion will only be obtained if the CRO's quality requires no extraordinary oversight. In my experience at four companies, use of CROs was warranted only to deal with unanticipated peak loads, in which case the additional cost and the additional oversight requirements were unavoidable. Nonetheless, I believe that large, well-managed pharma companies can realize greater improvements in cost, speed, and quality by more effective management of their own internal processes.

LEVINE. The areas of clinical services that have the greatest potential for growth are postmarketing surveillance studies, to meet chronic disease safety concerns; pharmacovigilence, to monitor cross-study product safety preapproval;

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Study Initiation and Patient Recruitment

C. LEE JONES IS PRESIDENT AND CEO OF THE ESSENTIAL GROUP INC., GURNEE, ILL., THE OPERATING COMPANY FOR ESSENTIAL CRO, ESSENTIAL PATIENT RECRUITMENT, AND AMERICASDOCTOR, WHICH IS A FULL-SERVICE CONTRACT RESEARCH ORGANIZATION IN THREE NICHE THERAPEUTIC AREAS AND A PROVIDER OF PATIENT-RECRUITMENT SERVICES IN A BROAD ARRAY OF THERAPEUTIC AREAS. FOR MORE INFORMATION, VISIT ESSENTIALGROUPINC.COM.

Study initiation/execution and patient recruitment are the two fastest areas where we are experiencing growth. In the next two years, we expect that rapid study initiation and completion and patient recruitment will continue to lead outsourcing efforts as drug sponsors of all sizes focus on rapidly starting and completing clinical trials.

The earlier in the planning process the better for maximizing the outsourcing partnering impact. Research from Vantage Partners and Accenture confirm this repeatedly. Early involvement of the service provider allows for better strategy and planning around the sponsor's needs. Earlier involvement contributes directly to improving the program strategy, design, and execution. The vendor has more time to plan and can deliver services in a more cost-effective and value-added manner.

Mandi Walters

METROPOLITAN RESEARCH ASSOCIATES

Ultimately, it's a CRO's consultative strengths that make it an invaluable partner.

between the amount of core clinical work being outsourced and being done internally, but there has been a rapid increase in the outsourcing of noncore tasks, especially those involving e-clinical technologies. As more companies realize that the administration, hosting, maintenance, and upgrading of software is not a core competency, they look to outsource those functions along with the continued development of systems that were originally developed internally. This includes increases in outsourcing of clinical-trial development using e-clinical technologies, such as EDC, electronic patient reported outcomes, and interactive voice response systems.

HERRING. While early-development services remain a strong area for growth, in 2004 there also was an upswing in late-stage development as the number of molecules in Phase III development returned to the highest level since 1977. As clients continue to demand greater access to patient populations, better project feasibility techniques will help identify geographical locations with extensive patient pools as well as recognize issues and risks before the conduct of the study. There also has been healthy growth in the early efficacy and safety phase of drug development, also known as Phase IIa. Because of increasing failure rates in Phase III studies, pharmaceutical and biotech companies are increasing their focus on more rigorous design of Phase II studies and establishing better efficacy measurements at this stage, before proceeding into full-scale, costlier Phase III studies.

PALLI. There is definitely a trend to outsource more and more functions in the clinical-development process. There also is an increasing need to outsource more of the same functions because as trials become more complex, outsourcing providers build centers of excellence in their knowledge of the different regulations and requirements. Sponsors frequently look to CROs to provide the required expertise. In the past, sponsors would outsource their overflow and develop their main studies internally. Now it is not uncommon for sponsors to outsource most of the main studies to use the expertise of the outsourcing providers.

data monitoring committees, to assess study safety; and technologies, inclusive of electronic and remote data capture, electronic submissions, clinical-trial management systems, performance metrics, and so on.

NORRIS. All areas that are not core or preferred competencies have the greatest potential for growth. These include ADME/tox operations, central lab services, and later-phase trials. Phase IV and other postmarketing efforts also are becoming areas where specific expertise outside of the biopharmaceutical companies are needed. A larger number of clients are outsourcing the fulfillment of various supplies in support of clinical trials, such as the printing of CRF pages. As the specialty sciences continue to expand and mature, service providers can find more organizations that need those related services and can justify a business model to offer those services. One particular area that sponsors are talking about is the ability to promptly and efficiently identify patients for participation in trials and then track their end-to-end participation.

GLIKLICH. We see tremendous growth opportunities for postapproval strategies and solutions. Part of the reason is that many companies do not yet have in-house expertise in this arena.

CLINE. In general, we still see a fairly even split

Dr. Richard Zakour

MCKESSON SPECIALTY

If organizations can establish preferred provider relationships in advance, that is the preferable way to go; it's the model that we use here.

KUBERSKY. We believe that IT services, as a component of the clinical-trial process, have great near- and long-term benefits for life-sciences clients. We view this segment as "low-hanging fruit" as organizations try to rationalize their cost structure relative to the trials process. IT outsourcing has been common in many industries for years but has lagged in life sciences primarily because of IP and regulatory issues. There has been a tremendous increase in the outsourcing of functions for a variety of reasons. Providers across the value chain have stepped up to make their offerings focused on market needs. With the need to contain costs, and at the same time achieve flexibility, only a well-crafted insource/outsource strategy will provide this balance. This business drive has forced organizations that have been historically reluctant to move toward outsourcing to do so.

ZAKOUR. There are three areas that we have identified: insulated shipping configurations, patient-compliance parameters, and monitoring of clinical trials. Many of the new biotech products require special handling such that they could require maintenance at a certain temperature at all times and a packaging configuration that will assure drug stability during the course of the clinical trial. The second area has to do with the packaging of drugs as they go into a kit for clinical trials. As clinical trials are becoming more complex and more detailed and undergoing closer scrutiny, it's important to ensure that the trial is conducted in the best possible manner; the kits need to be properly assembled, while maintaining the study blind, if required. There need to be good instructions, and kits need to be designed in a manner that is both patient- and site-friendly. In the area of clinical-trial monitoring, there are more requirements for patient and data monitoring. These aim to make sure patients are properly taking their medication.

WHERE?

Global capabilities are increasing in importance as sponsors look to untapped regions for their clinical trials.

PURCELL. It's really a mandate at this point to be able to do trials internationally. With technology solutions, the data can be collected and managed from a centralized location using fax and the Web. We are doing a trial right now at 81 sites in 18 countries, including India, South America, Africa, Europe, and the United States. Technology has advanced to allow us to efficiently manage these types of trials under compliance with 21 CFR Part 11.

GROSS. Companies are interested in doing R&D overseas, in China and India, because of the lower costs of drug development . A scientist in India might be one-fifth the cost of a U.S. scientist. The main problem with doing the development overseas is the potential loss of intellectual property. India and China do not have the same Western business values as we do. Sometimes companies think they can just go over there and do it on their own. But to operate in China and India with different cultures, it's often difficult. The best way to operate in those countries is to use a consulting firm that has people on the ground to assist with the process. In addition, there also is drug development going on in Korea and Taiwan.

BLANKSTEIN. Recruiting patients in a timely manner is still a major problem. CROs that have alliances with other CROs in different countries, such as Russia, China, Japan, India is critical. Mexico is hot right now. The problem is finding good clinical investigators in those areas. But I think this is improving.

DIBIASO. Despite the continued globalization of clinical research, most of the core expertise is still very much country and/or region specific. Global capabilities from an external provider are important but so too is the need to rely on the input and contributions of locally based resources. Too often there is an implied reliance on developing a global partnership without taking full advantage of the breadth and scope of those capabilities. For example, in the case of subject recruitment outsourcing, study teams might require a global vendor, but when it comes down to actually implementing a communications campaign, many of the participating countries are left to create and develop their own support for enrollment. In other cases, teams will select a vendor with limited global experience yet attempt to deploy poorly devel-

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EDC and Statistical Analysis Tools

PHILLIP LEE IS PRESIDENT AND CEO OF PHT CORP., CHARLESTOWN, MASS., A PROVIDER OF ELECTRONIC PATIENT REPORTED OUTCOME (EPRO) SOLUTIONS USED IN MORE THAN 150 TRIALS WORLDWIDE. FOR MORE INFORMATION, VISIT PHTCORP.COM.

We're experiencing increasing demand for our services, so electronic data collection solutions remain an area of growth. We see innovative statistical analysis tools that help sponsors determine the optimal size of a trial as another opportunity area as well. Fully integrated technology solutions, including wireless sensors that enable any type of data collection instrument or device to send data to a central location and to communicate with other devices, are also a great solution potentially for Phase I clinics. Other areas for growth our clients are asking for are online training solutions and patient-recruitment technologies.

An important part of our job is making sure the client fully understands the overall process of an ePRO implementation and how the technology changes current paper-based processes.

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Imaging

COLIN G. MILLER, PH.D., IS SENIOR VP, BUSINESS DEVELOPMENT, OF BIO-IMAGING TECHNOLOGIES INC., NEWTOWN, PA., AN INDEPENDENT, DEDICATED PROVIDER OF MEDICAL IMAGE MANAGEMENT FOR CLINICAL TRIALS. FOR MORE INFORMATION, VIIST BIOIMAGING.COM.

We have seen continual growth in the imaging portion of the clinical-trials sector over the last five years, both from the number of studies requiring medical imaging and the number of modalities being used in each study. Depending on the nature of the study, for a standard Phase II or Phase IV study, when the clinical team understands imaging and knows the requirements, two months before first patient is a good time to start.

For many studies entering into Phase III, we are now required to write an Independent Review Charter (IRC) for an approval by the FDA. This is a critical step to obtain Special Protocol Assessment (SPA) submission approval by the FDA. In these instances, we need to be involved at least two to three months before the SPA submission, which can be up to six or even nine months before the anticipated first patient in the study. These charters are not "cookie cutter" as many clients anticipate, and therefore, sufficient lead time is required for them to review and understand the read design and image collection methodologies.

Joseph Herring COVANCE

Both sides need to aspire to a good that is greater than the individual or group. While not easy to achieve, especially in science-based environments, this is critical.

oped materials across multiple countries. Both examples suggest an ineffective use and selection of the most appropriate outsource partner.

MALOFF. Given the advent of personalized medicine, geographic areas with populations that facilitate pharmacogenomics targeting will be hot. These are areas in which there are well-defined patient populations with minimal genetic drift.

NEF. Global capabilities are certainly a growing area. Not many CROs can claim to be a complete clinical organization. Some are stronger at CMC, or formulation, or marketing, or patient recruitment, and only a few are able to handle the entire process and to provide high quality in all domains. For the past few years, Eastern European countries have become important, China is now emerging, and the United States remains very attractive.

GODWIN. Many providers offer support for North America only. Sponsors and partners realize a service team representing the respective study regions is the best solution. Most people would say emerging markets are the hot geographic areas for trials. The top pharma markets, however, continue to be concentrated in America and Western Europe. The recent increase in drug-safety concerns and the interest in studying diverse populations within our

Timothy LaCroix

FLEISHMAN-HILLARD INC., CLINICAL TRIALS DIVISION

It often takes the initiative of a clinical project manager or his or her director to either work through the outsourcing group or work separately to identify the need for an incremental strategy.

home market indicates the hot geographic areas are still here. More important than hot geographic areas for trial opportunities seem to be persons of age and color. These are hot demographic areas for clinical research.

HUDAK. Global capabilities are important for enrolling patients, finding patient sources, controlling costs of clinical studies, and targeting growing markets. Eastern Europe, Russia, Asia, China, Africa, South Africa, the Middle East, and India offer a lot of opportunities. Providers can capitalize on these opportunities by developing ICH/FDA compliant services on the ground in those regions to take advantage of naïve patient populations and to make use of lower labor rates for clinical and data processes. These regions are typically underused until someone in the country has the capability to administer services locally.

GALLEN. Given recruitment difficulties in an already saturated North American and Western European market, there is clearly room for growth in trial-management services in India, China, South Asia, and Latin America. If a service provider could provide effective services in Japan, it would also be a huge boon to global drug development.

COULTER. Global capabilities must be taken into consideration when designing the overall outsourcing strategy. Today, we see opportunities being presented in Latin America, Eastern Europe, India, and, to a smaller degree, Asia. We look for partners that have local expertise with

GROWTH AREAS IN CLINICAL-SERVICE OUTSOURCING

PharmaVOICE asked experts from the leading clinical-trial service providers which outsourcing areas are expected to experience growth in the next two to three years.

Full-Service Trial Support

PAUL MILNE IS PROJECT DIRECTOR AT WESTAT, ROCKVILLE, MD., AN EMPLOYEE-OWNED CONTRACT RESEARCH CORPORATION SERVING AGENCIES OF THE U.S. GOVERNMENT, AS WELL AS PHARMACEUTICAL, BIOTECHNOLOGY, AND MEDICAL-DEVICE COMPANIES. FOR MORE INFORMATION, VISIT WESTAT.COM.

Clients are most frequently requesting full-service clinical-trials support, including project development and management, regulatory and safety management, site identification and management, site monitoring, data management, and analytical support. Clients are also increasingly asking for IVRS services for patient enrollment, randomization, and clinical-supply management. We expect this trend to continue.

Remote data capture services are continuing to gain popularity.

We also expect an increase in clients needing Phase IV postmarketing registry support following the recent FDA safety rulings.

Dr. Zev Munk

PHARM-OLAM INTERNATIONAL

Rescue missions usually emanate from poor communication between clients and providers.

Unreasonable expectations can result from feasibility studies and/or difficulties with study design.

an infrastructure committed to quality training according to ICH, and strong communication and planning. Cost is a powerful driver but without the necessary quality, knowledge, and experience with international collaborations, a relationship can be doomed to be both costly and damaging to a clinical program.

LEVINE. There are certainly circumstances where global capabilities are very important, especially when a sponsor company is looking for multiple-country approval and accelerated patient recruitment. Does this mean that sponsors should only consider companies with a global presence? The answer is no. There are many service providers that have established a global footprint through alliances that enable them to conduct clinical programs of this nature in a manner that is transparent to the sponsor. Sponsor companies should consider many factors, including therapeutic expertise, studies conducted in the various countries, and reputation of the provider in each country regardless of whether it's a single provider or an alliance of providers. The geographic areas that are currently hot are Eastern Europe and India, with China rapidly emerging. Providers can capitalize on these areas by being able to accrue patients that have become difficult to find otherwise and by applying strategies to study designs that may not have been considered before. As providers, we will be able to strive toward global standards and ethics, which will result in greater efficiencies, accelerated trials, and cost reductions in overall drug development.

MURPHY. Global capabilities are an absolute requirement for any technology provider operating in today's clinical environment. An ever-increasing number of the studies we work on use investigators in Eastern Europe, Latin America, and Asia. To provide better outcomes for clients doing studies in these regions, many local factors should be considered. Among these factors are: local regulatory requirements, investigator experience, infrastructure issues, language abilities/preferences, and cultural factors.

WALTERS. Global spending on clinical outsourcing is currently estimated at $7.8 billion. As trials continue to move from the United States and Western Europe, global capabilities will continue to be a key element for providers. Clients want providers who have access to naïve patient populations and large national hospitals. Geographic expansion will be crucial to the success of clinical trials as the market becomes more competitive. Because of the decreased cost of overseas trials, Eastern Europe, Latin America, Singapore, Taiwan, China, and of course, India have become the hottest areas for opportunities. These countries offer advantages, such as large pools of naïve patient populations, a wide spectrum of diseases, U.S.- and Western European-trained investigators, and lower costs. Providers can and should invest now in those regions. Many small- to midsized providers are entering into strategic alliances or partnerships with other regional providers that are experts in those areas. Larger companies are investing through acquisitions of other providers local to the areas. With either model, providers can gain a geographic presence.

KUBERSKY. At Ness we believe that the outsourcing of IT services has great short- and long-term potential. The short term is that some providers have already invested significantly to create a viable offering. With much of the prework already accomplished, there is great opportunity for a life-sciences company to gain immediate financial and operational efficiencies. With regard to geography, India remains a very strong market across all areas of

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Patient-Recruitment Services

ELIZABETH MOENCH IS PRESIDENT OF THE MEDICIGROUP, KING OF PRUSSIA, PA., WHICH BUILDS LONG-TERM CLIENT RELATIONSHIPS BY PROVIDING THE BEST STRATEGIC DIRECT-TO-PATIENT CLINICAL-TRIAL RECRUITMENT AND RETENTION PROGRAMS, COUPLED WITH WORLD-CLASS IMPLEMENTATION. FOR MORE INFORMATION, VISIT MEDICIGROUP.COM.

In the patient-recruitment field there is a significant shift in the way the projects are outsourced. In the early days, companies would outsource the entire patient-recruitment project without the availability of detailed forecasting or real-time metrics. Today, with a greater understanding of recruitment and its required flexibility to manage a dynamic and fluid process, companies are in-sourcing certain functions, such as development of a site-recruitment kit.

Meanwhile other aspects of patient recruitment continue to be outsourced: integrated phone/Web prescreening, real-time data tracking for ongoing recruitment support decisions, and placement of advertising.

John Hudak CRITERIUM

The relationship comes down to the people, their experience, their training, and their personality. These are the individuals with whom the client interacts.

outsourcing. There is great interest in Eastern Europe based on cost and multilanguage support. China is another growing market as the potential is very compelling.

MUNK. Global capabilities are very important. A company has to have the ability to place the correct study in the appropriate location. The main driving forces are the ability to recruit specific study populations rapidly, using the highest ethical standards and delivering quality results.

GLIKLICH. In a recent survey that we conducted with about 30 Phase IV trial sponsors, more than 50% reported that their studies and registries were in more than one country and in more than one language. Having the ability to deploy a global study or registry, or sometimes convert to a global study, is more important for some sponsors than others, depending on which markets they are focused on.

OLIVER. We're witnessing a lot of opportunities in some of the biotech hubs, such as Boston, San Diego, and Washington, D.C., where companies are relatively small and need to outsource quite a bit. Because they are in geographic locations where there isn't a huge pool of clinical talent to draw from, regionalization of clinical functions allows them to access more experienced people than they would get if they tried to hire the talent locally. Because of the challenges in patient enrollment, we're also seeing a lot of companies looking toward secondary and tertiary geographic locations, such as Little Rock, Ark., or Spokane, Wash., for clinical resources and investigator site locations. These smaller markets don't have as many competing studies, giving sponsors access to a patient population that hasn't been exposed to a lot of factors that would exclude those patients from enrollment. But to access those patients, companies need to grow their investigator database in these smaller markets and co-locate clinical resources, such as regional monitors. Providers that can identify and hire these resources in the smaller markets have an advantage.

WHEN?

Most experts agree that outsourcing partners should be brought in the development cycle as early as possible.

BLANKSTEIN. I believe the earlier sponsors can make the decision to bring on a partner the better, whatever the service is for, whether it's patient recruitment, data management, or clinical monitoring. The CRO then has a really good understanding of what the sponsor's needs are and becomes a part of the team. When a sponsor brings in a CRO later, it's usually because of a crisis.

MALOFF. The question really is: "who owns outsourcing?" If the decision belongs to a centralized procurement/outsourcing office, then the services partners all look pretty much the same. Once the basic criteria are met — financial stability, size, scope, experience — the decision is based on price. Price might be an appropriate strategy for a pharma company's outsourcing decisions for payroll checks or overnight shipping, but it's a stunningly shortsighted approach to outsourcing research and development. A day's delay for a major drug because of underperformance by a services company, be it in discovery or Phase III, is going to cost $3 million in lost sales. Outsourcing partners should be brought in at the level of resource allocation, with selection driven by the therapeutic teams that depend on their performance and insights. Taking it to the next level, sponsors and partners that can plan and execute integrated approaches — gaining efficiencies between discovery, preclinical, and clinical — are the ones that will set the pace for the industry.

LACROIX. It often takes the initiative of a clinical project manager or his or her director to either work through the outsourcing group or work separately to identify the need for an

Dr. Richard Gliklich OUTCOME

We see tremendous growth opportunities for postapproval strategies and solutions. Part of the reason is that many companies do not yet have in-house expertise in this arena.

David Kubersky NESS TECHNOLOGIES

Information technology services, as a component of the clinical-trial process, have great near- and long-term benefits for life-sciences clients.

incremental strategy, for example, centralized patient recruitment. The complexity that sometimes exists comes from the lack of an integrated outsourcing process, and secondly it may be more difficult for both the outsourcing group and the clinical team to come to grips with the ROI analysis. In other words, the team may decide to spend an additional X% of the direct budget to accelerate enrollment, the direct outcome of which isn't necessarily immediately apparent; it may take several weeks to kick in. Obviously the payback should be patients enrolled sooner, thus shortening the entire study timeline, which can, of course, impact budgets immensely. Every month a company saves on a clinical team not being involved in a study can yield incredible time savings. When companies look at the impact of a really solid, strategic patient-recruitment plan and implementation on their timelines, the results can be huge. It's not about saving a week or two after database lock. In some cases, we are talking about saving months.

NORRIS. The decision of when to outsource should be driven by the results of a thorough analysis, where an organization's SWOT — strengths, weaknesses, opportunities, and threats — are identified. Too often pharmaceutical/biotechnology companies make the decision on timing based solely on broad assumptions that involve review of immediate resource constraints. We advise clients to make a timing decision dictated by a thorough assessment of their SWOTs, relative to their organizational dynamics, while determining three- to five-year strategic goals and existing portfolio. This exercise enables companies to time outsourcing in light of immediate needs and long-term strategy. It also aids in choosing a vendor that can be leveraged for the sponsor's strategic goals and sets the foundation for a true partnership. The overwhelming point is that a firm must bring in outsourcing partners as part of a proactive strategy, whereby they complement the organization's core mission and competencies. It's never too early or too late to create a relationship with an appropriate partner for services.

DIBIASO. Pfizer has been focused on addressing strategic recruitment planning and outsourcing considerations at a clinical-research "program" level as opposed to a single protocol level. This might occur up to 18 months before a series of studies is being initiated. Taking advantage of these early discussions enables us to assess required external expertise while still having the ability to influence and modify planning for multiple studies. My belief is that the industry is doing a better job addressing patient recruitment at a protocol level but I believe we should really initiate planning during the conceptual program level. This means that instead of addressing recruitment for one or two studies, we can start to think about longer-term strategic recruitment needs, outsourcing requirements, and desired expertise for an entire therapeutic program or compound development program. If we can begin discussions at this time, we could take full advantage of the expertise from an outsourcing partner long before a series of studies advance through development. The conventional wisdom is that by the time patient-recruitment planning gets to the protocol study team level a lot of the critical success factors for enrollment would be in place.

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Phase I Studies

EDWARD SELLERS, M.D., PH.D., IS PRESIDENT AND CEO OF VENTANA CLINICAL RESEARCH CORP., TORONTO, A DEDICATED CLINICAL RESEARCH FACILITY WITH AN IN-PATIENT CAPACITY OF 64 BEDS. FOR MORE INFORMATION, VISIT VENTANA-CRC.COM.

To meet clients' growing demands, we have recently quadrupled our capacity for Phase I specialty studies. In our five-year plan, we project this demand will grow at an increasing rate; pharma companies and biotechs are investing more heavily in early-phase studies to screen compounds to increase the probability of success in later stages when study costs are significantly higher. Another related factor is the number of pharma companies that have closed, or are considering closing, their internal clinics and outsourcing key projects.

In our experience as a provider of early-phase studies, we find that the most successful projects begin with understanding the entire drug-development program. When we are able to realize the context for a study and how it fits into the overall development program, we can work with the client to determine realistic timelines and appropriately set expectations based on deliverables.

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Patient-Recruitment Services

ANGELIQUE SWANN, OPPORTUNITY DEVELOPMENT DIRECTOR, (PI) PATIENT INTERACTION, POMPANO BEACH, FLA., WHICH OFFERS A SUITE OF SERVICES TO CAPTURE PATIENT INTEREST TO FACILITATE, ACCELERATE, AND ENHANCE CLINICAL-TRIAL ENROLLMENT AND RETENTION THROUGH AWARENESS CAMPAIGNS, PATIENT EDUCATION, AND DIRECT-RESPONSE MEDIA. FOR MORE INFORMATION, VISIT PATIENTINTERACTION.COM.

We have recognized an increase in two areas: sponsors that are looking for enterprise solutions for large, global trials and for solutions for minority or special populations for niche clinical trials.

Providers can help sponsors with national and global trials by streamlining the production and fulfillment through the use of preapproved, customized patient-recruitment and retention materials.

By using a Web interface, as well as materials that can be translated into foreign languages, it makes the management of the entire process, including tracking usage and results, much more efficient. With regard to recruiting minority and special populations, knowing how best to target recruitment campaigns in print, radio, television, and online can help enroll a trial on time and within budget, bringing the product to market faster.

Jim Murphy

INTERACTIVE CLINICAL TECHNOLOGIES INC.

There is no one-size-fits-all approach to good provider/client relationships.

HERRING. In drug development, there are definite advantages to strategic relationships versus tactical, case-by-case work. In my opinion, strategic relationships can reduce — perhaps even eliminate — the need for rescue work, as clients and providers continually strengthen their ability to communicate effectively and to work together to achieve the shared goal. A strategic relationship with a provider — or at least a multiple-service agreement — also generates time and cost efficiencies for the client. Conducting several development services in parallel, rather than in sequence, definitely saves both time and money. Longer-term strategic collaborations and multiple-service projects enable clients and providers to bring new medicines to the market as quickly and efficiently as possible.

COULTER. Outsourcing decisions are often triggered by conditions that were unforeseeable. Nevertheless, sponsors and providers can still plan effectively to optimize the chances for success. Thoughtful outsourcing strategies that leverage the sponsor's core strengths and capitalize on those of the provider can be the key to success, provided that the client sticks to the intent of the original plan. Midcourse changes can be detrimental to both client and provider.

CLINE. In clinical research there is little room for error and huge opportunities to be lost with delays. When a project falls outside a pharmaceutical or biotechnology company's core competency or is a new approach, it is time to bring in help. A provider's top responsibility is to make a process easy for the client. By selecting a provider that not only offers the best tools but is also easy to work with, pharmaceutical and biotechnology companies can truly reap the benefits of an outsourcing partner. A common mistake is buying a technology when what the sponsor really needs is a technology partner. An experienced partner that understands how to best meld technology and process to make clinical research more effective is always a more practical solution than software alone.

LEVINE. For any relationship to be successful, information has to be shared on a timely basis. When a service provider is brought in early in the development cycle, it has the opportunity to learn not only about the product, but the individuals as well. The service provider is intimate with the development details, and as a result, can proactively assist with a winning strategy.

LAGROTTERIA. From a CRO's perspective, it would be extremely helpful for sponsor companies to bring in service providers months before there is a need for services. This would allow for a couple of actions. First, there would be a complete understanding by the sponsor companies of which service providers are truly interested in helping them achieve their objectives. Secondly, this would enable service providers to proactively identify and commit project teams way before study kick-off, thereby eliminating any last-minute rush to pull together a project team.

PALLI. The earlier a provider is involved the better the outcome. We don't mind rescue missions as long as the study can be salvaged. Unfortunately, there are times that avoidable mistakes have been made up front and require a lot of extra time to be corrected and, in the clinical-development process, time is money. If a CRO is involved during the strategic planning phase, it can help design a study or a clinical-development plan to expedite the process while adhering to the regulatory standards. The trend now is for what historically were considered "back-end" providers to get involved earlier, such as during the strategy phase, because of the increased focus on the data component for both regulators and sponsors.

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Cardiac Safety Assessment Services

POLINA VOLOSHKO, M.D., IS VP OF CARDIOVASCULAR CLINICAL SERVICES AT GENTIAE CLINICAL RESEARCH, SAN FRANCISCO, AN INTERNATIONAL PROVIDER OF CARDIOVASCULAR CORE LABORATORY SERVICES, INCLUDING ELECTROCARDIOGRAPHY (ECG), HOLTER, ECHOCARDIOGRAPHY (ECHO), ANGIOGRAPHY, PET, AND MUGA. FOR MORE INFORMATION, VISIT GENTIAE.COM.

The clinical services that have the greatest potential for growth include drug screening and testing; Phase I services; diagnostic testing; cardiac safety; and data management, especially tools that can integrate data from various disciplines to be used for design of future studies.

As a core lab, we have experienced an increase in cardiac-safety assessment services because of the recent FDA/ICH regulations and drugs being pulled from the market for safety concerns. Echocardiography is being used more often for detecting safety issues in oncology clinical programs.

Mark Levine AVERION

By collaborating effectively, the sponsor and provider can adjust accordingly for a successful and mutually rewarding outcome.

improved include better communications and preferred provider relationships.

HIGGINBOTHAM. We find that it is best to establish relationships with biopharmaceutical customers as early as possible in the development process. This enables us to develop a better understanding of their outsourcing objectives and timelines and creates an environment for ongoing scientific collaboration, ultimately leading to a more proactive, flexible approach to drug development and operational efficiencies and resulting in reduced cycle times.

BISHOP. The majority of companies bring in outsourcing partners very late in the day. From our perspective, in many cases this can be after critical decisions have been made and implemented that can impact our ability to design or deliver an optimal service based on the needs of the protocol. Clearly, any earlier discussion, for example, at time of protocol concept, will help the outsourcing partner determine project needs better as well as be able to track changes in protocol design that may impact potential services that are being planned or built to support the protocol. Importantly, understanding that there may be changes in certain aspects of the protocol may also help the outsourcing vendor to plan delivery activities around those potential changes and avoid changes in scope and associated cost/time implications.

HUDAK. The sponsors need to admit to themselves earlier in the process those areas in which they might need a CRO. Oftentimes, the decision gets made at the last minute, when resource constraints are at a critical point and the sponsor then does not have the time to do its own due diligence and meet its timelines. Hasty decisions are made. Partnering is a way to improve the outsourcing process with its implications of due diligence before starting a project and tight communications with people, processes, and technology with which the company is familiar. Each CRO has different characteristics and strengths.

HOW?

Some of the strategies experts identified as to how the outsourcing process can be

NEF. The outsourcing process can be improved by defining "hubs" of a few good providers, negotiating an overall deal based on risk sharing, and ensuring a constant flow of molecules to develop. Once these strategies are in place, a senior alliance manager should be controlling and modifying the contract, if needed, and tracking milestone achievements.

SERODY. Preferred provider relationships are a mixed bag. The positives are prenegotiated master service agreements, rates, and the familiarity of ongoing relationships. In speaking with some sponsors, there is also a recognition of its limitations. Limited access to services and providers that might fall out of the range of the list is a continuing concern. I have been told that the process for using a provider not on the list can be so time consuming that, in the end, the company has a listed provider performing a task that it might not be best-suited to deliver. I believe clinical-service providers and sponsors are seeking the same end result, which is to end up with the best partner for delivering the trial.

ZAKOUR. In my opinion, if organizations can establish preferred provider relationships in advance, that is the preferable way to go, and it's the model that we prefer to use at McKesson BioServices. We can frequently work out many of the details ahead of time and even work through mock situations. If the table is set before the project even starts, we can often anticipate any glitches or bumps that might happen along the way. In addition, there is the opportunity to open the lines of communication to find out where there might be gaps and then try to integrate the properties as much as possible. Clearly, one of the key things is to be sure that the sponsors and providers are totally comfortable working with each other; then that relationship can be leveraged for ongoing as well as for future projects.

LACROIX. I believe there will continue to be a mix of approaches, and, of course, there will always be the companies that want to focus on two, three, or four providers. On the other hand, there are a number of companies that

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Pharmacovigilence

TOM WARDLE IS SENIOR VP, CLINICAL RESEARCH OPERATIONS, AT I3 RESEARCH, BASKING RIDGE, N.J., A FULL-SERVICE, GLOBAL CRO SPECIALIZING IN ONCOLOGY, CENTRAL NERVOUS SYSTEM, AND RESPIRATORY AND INFECTIOUS DISEASE. FOR MORE INFORMATION, VISIT I3RESEARCH.COM.

We have experienced significant growth in our oncology clinical-research services business. Over the next two to three years, we expect that the CRO industry in general will experience a significant expansion in services related to Phase IV trials and pharmacovigilence.

Heightened awareness of drug safety by governmental agencies, as well as the need for big pharma and biotech to expand the indications of marketed projects, will fuel this expansion.

We also expect to see continued strong growth in epidemiology, health economics, and outcomes research services because of the continued emphasis on efficient use of healthcare services in the United States and Europe. Scientifically rigorous studies of drug safety will be necessary to meet the needs of regulators, manufacturers, consumers, payers, and healthcare providers. Outcomes groups will need to have sophisticated tools and strong expertise to gain a deep understanding of the economics of healthcare.

Kim Oliver KFORCE CLINICAL RESEARCH

Because of the challenges in patient enrollment, we're seeing a lot of companies looking toward secondary and tertiary geographic locations.

have not embraced this approach. And we've seen in the last two or three years a little bit of a push back from sponsors in terms of the very rigid preferred provider agreements.

HERRING. In my opinion, clients and providers face a critical choice in today's ultra-demanding industry environment. We can collaborate or we can stagnate. I firmly believe that the most productive collaborations are built on longer-term strategic relationships. Again, that's why I emphasize the importance of both clients and providers living up to values that put in place a strong foundation to build trust and teamwork. While these values create opportunities for a strong future, they will not change things overnight, and we have to take immediate steps as well. In contract negotiations, for example, clients have to be clear about their needs and expectations, and providers need to be flexible but realistic. Building trust is a two-way street. For providers, that means not promising something that they know they can't deliver in the agreed-upon time and cost parameters. For clients, that requires clear up front communication. Clients and providers should actively work toward multiple-service agreements and preferred relationships whenever possible. These are good for everyone.

BLANKSTEIN. Within Genzyme, from team to team, it varies as to how much involvement the CRO has. I think it requires some pushing from the CRO to say it knows the best way it can serve us, try to understand the various aspects of the program, and to incorporate its services into whatever we are doing. Even though sponsors want to have this partnership, I think there is a reluctance on our part to really involve the CROs as much as they need to be involved to be most successful. I believe the other key aspect to the relationship is problem solving and risk taking; risk taking should be shared, and this can take many forms. There need to be agreements up front in terms of what the risks are if certain goals and expectations aren't met, whether it be financial risk or resource allocation risk.

GLIKLICH. Although initially it may take more work than going to a large CRO, there is great benefit for outsourcing groups to research niche expertise that may not be within a company's usual preferred provider relationships. Too often, preferred or just historical relationships lock in groups that may not be best in class for a particular type of clinical-research program. The technology for a Phase IV study or the management of a safety registry is very different from technology and management of preapproval studies. There are many other examples as well. Outsourcing groups need to do their homework and not assume that a preferred relationship in one scenario will provide best-in-class capabilities in another scenario. Finding the correct vendor can be the difference between a successful strategy and study and a study filled with "miscues."

PURCELL. I don't think communication channels are set up properly because people have different agendas and are busy with their own jobs. And I don't think that project management is taken as seriously as it should be. From the budgeting standpoint, the biggest complaint I hear from every sponsor, large and small, is "what are all these project management costs? They are too expensive; take them out." But if I take out the costs, sponsors don't get the project management that is required to manage their projects appropriately. Project management should typically be 20% to 30% of the total budget, if it's being done right. Sponsors don't want to pay that much. But without a project manager, there is no central point of communication, things get overlooked, there is no one person accountable for being on top of the project. Every project requires an individual who has an understanding of all aspects of a clinical trial, from monitoring and site management, to data management, to analysis and reporting. The lack of focus on project management also hinders communications within the pharma companies. The people who are designated project managers within the sponsor have so many pieces to fit together that they have a hard time communicating internally with their own teams because people and departments are so disparate, both geographically and philosophically.

GODWIN. Preferred provider relationships streamline use of clinical providers for the actual purchaser of the services. Yet these models can be a bottleneck, too. Incorporating an "exception policy" would be a favorable approach. This would allow those purchasing the flexibility to choose a "best-fits" approach.

WALTERS. Many companies still view providers as vendors or suppliers. This perspective creates an environment where information is not shared and the relationship is not optimized for success. The outsourcing process can be improved by managing the relationship differently. If some level of integration were put in place when the provider is chosen, the teams would be better positioned to share information and respond more quickly to needs. Streamlining the procedures required to manage the clinical-trial process would allow clients to focus on managing the actual sponsor-provider relationship as opposed to managing specific tasks.

DIBIASO. From a recruitment perspective, we believe that there are no short cuts to the process. Each one of our outsourced partners has a unique expertise or core contribution that must be assessed and then matched to the specific needs of our study teams. While providing contracting and other costing efficiencies, preferred partnerships for recruitment vendors might limit our ability to capitalize on niche or innovative service providers in a rapidly changing marketplace. I want to be able to take advantage of a great new technology or service, which might be limited by a preferred provider system for clinical-trial recruitment.

OLIVER. The best way to improve the outsourcing partnership is to take a long-term approach to the relationship, such as codeveloping the dynamics of the working relationship and allowing the outsourcing partner to act as a consultant. Rather than dictating precisely what they need to do and how to do it, sponsors should make use of the expertise providers have developed by working across multiple companies. There should be shared risks and successes in the relationship. By cultivating a true partnership, the end result will be lower costs in the time and resources required to get new projects up and running as the partnership grows more efficient. This type of preferred provider relationship will eliminate the time required and business development costs that are incurred every time bids must be sent out to multiple CROs. Finally, minimize the points of contact between the sponsor and provider for both business and clinical needs. This simplifies communications and helps prevent the misunderstandings that can happen when too many people are talking at the same time.

MALOFF. As an industry, we need to do a much better job of characterizing patient populations before they are considered for trials. Better patient information ranges from the fundamental, i.e., basic phenotype profiles to meet inclusion/exclusion criteria, to the more strategic. For example, patients can be profiled for P450 enzyme activity to preclude ultra-rapid metabo-

The Partnering Process: A SPONSOR'S POINT OF VIEW

There is so much at stake in selecting the best vendor for a particular project that this process should be considered to be of high importance, analyzed for effectiveness, and reengineered to improve its results. With the success of a project at stake and the risk of losing large amounts of money and time, this selection process should not be taken lightly. There are methods that cost nothing and can be easily implemented that can improve the chances that the vendor selected by the sponsor is a good match for the long haul of a project.


SHERRY REUTER, B.S.N., M.S.

The following changes in the process of selecting vendors have been made at a major pharmaceutical company, with results demonstrating that these changes can be a win-win for all parties involved.

Rather than potential vendors meeting primarily with the grants and contracts department, much more can be accomplished by including the team that the vendor will actually support in the selection meetings. This allows the people who will interface the most with the vendor to have an opportunity to engage in discussions pertinent to the project. Interpersonal style can be assessed for the best fit as well as information presented by the vendors, allowing the team to make a better selection. Since all parties have very limited time, these meetings are most productive if carefully structured.

Vendors are told that they will have five minutes to very briefly present information about their company. If the attendees select the vendor, there is plenty of opportunity for the grants and contracts department to obtain other information at a later date.

Vendors are told that their total presentation will last only one hour. This requires the vendor to plan a concise presentation, while assuring busy team members at the sponsor that they will be able to make good use of the one-hour meeting and that the information in which they are most interested will be presented, rather than the topics presented in the old "dog and pony show" that are not germane to selecting the best partner.

At initial meetings, vendors come prepared to present topics as stated by the sponsor when the invitation to explore the possibility of partnering is extended. The sponsor's team determines what criteria are most important in selecting a vendor for the specific project and specifies what type of presentation would address that issue. This allows the team to compare all the presentations, which all conform to the same content and time requirements, to select the presentation that best addressed the key need.

Presentations that would be most helpful to the in-house team include case studies of a key aspect of the proposed project, a presentation of the vendor's past-recruitment program(s) for the specific indication, metrics of the success rates of methods used in the past in similar situations, and specific improvements the vendor would suggest. Case studies have been especially well-received because they provide relevant, interesting information in a short amount of time.

Vendors are told that they should come prepared to present metrics related to their experience and success rates rather than stating general claims. This setting provides an opportunity for the team and the vendor to get to know each other in a more realistic setting instead of using the time on a general sales presentation that may be of little relevance to whether that company would do the best job. The parties get right down to business — brain-storming solutions to the specific project.

This structure is a win-win for all parties.

Source: Sherry Reuter, B.S.N., M.S., Senior Clinical Project Leader, Alexion Pharmaceuticals Inc., Cheshire, Conn. For more information, visit alexionpharmaceuticals.com.

The Partnering Process: A CRO'S POINT OF VIEW

Sponsors can derive the maximum contribution from a strategic alliance or partnership with CROs that offer a broad range of clinical development services, extensive experience, and global reach, combined with high-quality standards. The relationship must be strategic and not a last-minute "out-tasking" exercise, if all benefits are to be realized. One important criterion that is missing from many relationships is trust. If following careful and comprehensive due diligence, a decision is made to proceed with a provider relationship, then trust must be part of this relationship.

Key elements to establishing a solid partnership include:

- Commitment at all organizational levels, particularly senior management.
- Shared goals and objectives at relationship onset.
- Communications streamlined at all levels.
- Adoption of standard operating procedures and optimal use of systems.
- Financial benefits to both organizations agreed to and monitored.

COMMITMENT

As one considers how the sponsor and the CRO can maximize the benefits of a strategic alliance, it is clear that success requires substantial commitment from both parties. Accordingly, a CRO anticipates that a preferred provider agreement is of sufficient duration and dollar value to justify the commitment of critical resources and personnel. This resource commitment enables the two companies to forge an ongoing business relationship that greatly enhances the already substantial value that each derives from the partnership.

GOALS AND OBJECTIVES

Certainly a key component of an alliance or partnership is sharing common goals or objectives. Part of the process is to identify these goals early in a relationship. These may range from project specific (i.e., date of first patient in, database lock), to program specific (i.e., completion of enrollment for Phase III studies), to even broader, higher-level objectives such as NDA or MAA submissions and submission dates. To derive the greatest benefit, it is ideal if the sponsor shares its goals and objectives at all of these levels, and further, the CRO should be measured and incentivized by these clearly defined goals, described early in the calendar year or at the beginning of the sponsor's annual planning process.

COMMUNICATIONS

Sharing of objectives at a high level is an appropriate start for the extensive communications that a successful business relationship of this type requires. Regular communication between the companies assures attainment of high-level goals and objectives, project- or process-related. An important element of communication is sharing the timing of new projects. This enables the CRO to manage its resources optimally, providing the sponsor with the most therapeutically experienced people for the upcoming projects and maximizing its use of resources. Another key benefit of senior-level communication is effective, proactive organizational leadership and direction.

STANDARD OPERATING PROCEDURES


BILL TAAFFE

Ideally, the sponsor and CRO strive to share both systems and processes whenever it is practical. Common systems and tools, or seamless integration for such, have the obvious benefit of facilitating the transfer and manipulation of information both within and across the two companies. Commonality in processes better aligns the organizations, and reduces the chances for problems that relate to how specific tasks are completed.

FINANCIAL BENEFITS

A multiyear agreement, which includes the designation of dedicated liaison personnel on both sides, enables the companies to become increasingly familiar with one another, to climb the learning curve, and ultimately to function more efficiently. Additionally, the sponsor realizes financial benefits, such as negotiated rates and rebates. Use of multiple services (bundling) also will lead to significant savings and greater efficiencies.

Regardless of whether outsourcing represents the principal approach to clinical research, an approach to peak resource requirements, or an approach to access select patient populations or geographical areas, contract research is a solution that has grown — and will continue to grow. Increasingly the question isn't whether to outsource, but rather how to get the most benefit from an outsourcing relationship with a CRO to conduct clinical trials.

SPONSOR BENEFITS TO PARTNERING WITH A CRO

Choosing to work with a CRO to conduct clinical trials can enable a number of potential benefits to sponsors:

- The in-house, full-time development staff can be minimized.
- Sponsors can access experienced clinical-research professionals who have expertise in the therapeutic area and indication being studied.
- The CROs can often provide a pool of investigators with both experience in the area of study and a pool of potential patients.
- The CROs can provide services needed to conduct the study in the desired part of the world.
- CROs have refined the drug-development process ("it is all we do") by investing in the technology that will deliver their primary product, data, in a timely and quality manner.

Source: Bill Taaffe, President and CEO, ICON Clinical Research - U.S., North Wales, Pa.
For more information, visit iconclinical.com.

Dr. Bruce Maloff INVITROGEN CORP.

Given the advent of personalized medicine, geographic areas with populations that facilitate pharmacogenomic targeting will be hot.

lizers and slow metabolizers from trial populations, allowing the drug candidate an enhanced opportunity to demonstrate efficacy in the responder population.

GALLEN. Having been in the CRO business for some years and now on the other side of the negotiation table for several years, what I find absolutely critical is for CROs to get it right during the bid process. One key is to reduce the overhead of contract negotiations by using master service agreements with preferred providers so that initiation of a given contract is really essentially a work order with most other aspects already covered in the MSA. Secondly, vendors need to provide contract bids in a format that is transparent, spelling out costs and assumptions up front and making readily interpretable comments related to the study at hand. I don't think CROs realize how much business they lose because their bids are not interpretable or simply reflect a misunderstanding of the study.

NORRIS. Service providers need to do the same soul-searching and self-inquiry that sponsors must do. They need to examine their own mission and identify the core competencies of their enterprise and then decide strategically which services they will provide and which services they will outsource. CROs will need the same access to externally provided specialty services that sponsors require of them. If a CRO's specialty is clini-

Ames Gross PACIFIC BRIDGE MEDICAL

Companies are interested in conducting R&D overseas, in China and India, because of the lower costs of drug development.

GROWTH AREAS IN CLINICAL-SERVICE OUTSOURCING

PharmaVOICE asked experts from the leading clinical-trial service providers which outsourcing areas are expected to experience growth in the next two to three years.

Optimized Lead Selection

DAVID C. ZIMMERMANN IS CEO OF KALEXSYN INC., KALAMAZOO, MICH., A PROVIDER OF MEDICINAL CHEMISTRY SERVICES TO SCIENTIFIC CUSTOMERS ENGAGED IN THE DRUG-DISCOVERY PROCESS. FOR MORE INFORMATION, VISIT KALEXSYN.COM.

Optimized lead selection and exploratory clinical studies will allow for the larger, more expensive Phase II-III studies to be conducted with a higher likelihood of success. Just as biopharmaceutical issues are less frequently responsible for late-stage failure of compounds now than in 1990, development of rational exploratory clinical approaches, integrating innovative study designs with new technologies and targets, will reduce attrition due to lack of efficacy or unexpected toxicitylate in drug development.

Microdosing is an emerging approach that can efficiently provide human data for lead compounds faster, with less API and preclinical data needed before dosing.

Achieving improved early clinical success offers the greater outsourcing of bundled services before committing to a full development and registration is feasible, especially for small- to midsize pharma that may lack specific areas of expertise. Their internal experts can thus serve as high-level project champions and guides rather than building operational infrastructure. Particular emphasis on developing rational project strategies, identifying suitable partners to deliver specific components, and integrating, warehousing, and mining the data and reports from the project are all areas for significant growth.

New R&D efforts are frequently target-based, and companies frequently try to assess both the target(s) and the compound intended to affect the target in the same clinical study. This generally raises more questions than it answers.

Richard Purcell CLINPRO INC.

The best way to market drugs is with data. The data have to be clean and they have to be analyzable. The way to get to these clean data packages faster and better is through technology.

cal-trial management, it may need to contract with an external or offshore capability for patient recruitment and screening. Both sponsors and CROs need to identify their core mission and then implement the programs to identify, cultivate, and manage the relationships with providers of services that best complement their own strategic offerings. Another big issue that should be addressed is metrics. Sponsors and CROs alike must establish thoughtful and actionable programs of metrics to measure the ongoing success and performance of the services being delivered as well as the services that keep the partnership on track. Both types of firms are showing a growing interest in moving these relationships onto a more "evidence-based" footing, allowing both sides to monitor and respond to issues and opportunities to improve service delivery.

MUNK. Lack of compromise and lack of openness has led many relationships to land on the "rocks." Both partners must be flexible with their mutual needs, and goals must be integrated into a formal relationship. There should be leeway for contingencies that may arise. A relationship that starts off with one party feeling "taken advantage of" may lead to frustration and skepticism throughout the project. Preferred provider status recognizes the contributions of a trusted partner. This type of relationship may enhance cooperation and eventual performance. On the other hand, many sponsors have realized that keeping the "door open" may lead to a more competitive environment, and they may realize their goals quicker.

COULTER. In the end, outsourcing is a relationship business, and it is impossible to be successful without clear, routine communications that support both parties' expectations for a successful project. With a baseline of competency in the functional disciplines, it is then imperative to invest in the development of relationship management skills to create partnerships based on trust. A project is unlikely to be successful unless both parties fully understand and support the plan that has been agreed upon in advance. Therefore, open and realistic communication between client and provider is the most important factor in improving the outsourcing process.

CLINE. It all gets back to trust and communication. Service providers are in the business of helping their partners achieve significant cost reductions and process improvements. Providers are most effective when clients share their goals with them and trust them to develop a plan that works for both parties. We believe very strongly in the concept of partnering to improve the efficiency of clinical research. With preferred provider relationships, a provider has the opportunity to really prove the value of partnering over a series of trials. Providers can demonstrate how reuse can drive down development costs and how a number of trials impact the traditional hardware-related startup costs. Enterprisewide adoption, with the help of a provider with experience and the resources to help in integration, allows pharmaceutical and biotechnology companies to benefit immensely by taking advantage of the expertise their outsourcing partners can offer.

PALLI. It would be ideal to form preferred provider relationships based on mutual understanding, respect, and trust. The benefit is that the provider and sponsor spend less time on the logistics and learning each other's style, so both can concentrate on the study at hand. Preferred provider relationships work well as long as complacency is avoided. No matter if the provider and sponsor work together for the first time or the hundredth time, a well-written RFP with clear delineation of responsibilities and assumptions sets the right direction.

HIGGINBOTHAM. CROs need to get to know their customers very well and to understand their business philosophies and their unique requirements. We believe preferred provider relationships offer a mutually beneficial approach to outsourcing for CROs and biopharmaceutical companies as they lead to significant efficiencies. To develop a relationship at this level and truly deliver the value that is created through a long-term partnership, CROs must be involved early on in the development process, be treated as partners versus "hired help," and participate in the planning of programs as opposed to just responding to individual requests.✦

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