BY ROBIN ROBINSON

Creating Global Clinical Connections

A successful CRO/sponsor partnership is much like a marriage; it requires trust, communication, and a commitment to best practices by both parties.

According to The Centre for Medicines Research International Ltd. in 2005 almost 50% of patients recruited for clinical trials came from outside of the eight core countries — Canada, France, Germany, Italy, Japan, Spain, the United Kingdom, and the United States. Both big pharmaceutical and smaller biotech companies are increasing their use of CROs to gain world penetration. Therefore, it's more important than ever that all parties are on the same page and develop a model based on a true partnership. Expansion into emerging markets necessitates a high degree of global consistency and team integration between sponsor and CRO. Our Forum experts offer strategic and tactical advice for approaching the challenges in cultivating better relationships between CROS and sponsors in this situation.

Building Relationship Bridges

Forming a winning CRO/sponsor partnership requires trust, communication, and understanding the expectations and needs of the other party. Using advanced technology for communications, taking ownership, and getting to know your partner can ensure these elements are front and center of the relationship.

GUTHRIE. XCELIENCE. Probably the single most important element required to form a solid partnership revolves around truly understanding the needs of both parties. With that in place, communications, decision points associated with successes and failures, and outcomes become more logical. Clearly, these usually emerge from a great deal of up-front time or relationship experience before moving into a partnership arrangement. Any partnership that mismatches capabilities versus needs can be doomed from the onset.

GRIFFITH. APTUIT. Structured, transparent communications on both sides of the project are essential to a successful global partnership. This commitment to transparent communication should happen across various levels, such as: dedicating a project manager located in the specific market and time zone in which the client operates; maintaining a project-specific Wiki that serves as a digital information repository; and holding daily conference calls and quarterly steering committee meetings. Each of these important communication components avoids gaps in information that slow the decision-making process, as well as provides real-time access to and support for projects around the clock. For example, rather than simply providing a brief of the day's activities, a Wiki can be created on a secure Intranet for each project. Staff members in North America can upload their lab notes, scan in useful documents, and write other comments about the project, creating a digital information repository that allows someone working on the project in, say, India to collaborate in real time.

TYSON. CAMPBELL ALLIANCE. Trust is what it's all about. For a sponsor and CRO to have a successful partnership, both sides need to establish trust: trust from the sponsor's perspective that the CRO is providing the most appropriate staff and working as efficiently as possible to keep costs contained; and trust from the CRO's standpoint that the vendor's perspective is being considered and that the sponsor is not taking advantage of the partnership.

PAGE. I3. There has to be transparency into the respective organizations with open communications about resource capabilities and performance expectations. A solid global partnership requires trust, a complement of expertise, a true expectation of resourcing needs, and an understanding of regional differences and their influence on the work to be completed.

THE SINGLE MOST IMPORTANT ELEMENT REQUIRED IN ANY PARTNERSHIP IS GENUINE COMMITMENT.
For expectations to be met on both sides, there must be a true intention to form and maintain a global partnership with recognition that there is mutual dependency.

Josef von Rickenbach. PAREXEL

HARTE. ETRIALS. The single most important element is trust — the feeling of having a partner that is operating in your best interest, contributing as a team member to offer advice and guidance, and participating as an active member of the team.

GEATZ. INCLINIX. The single biggest challenge for a CRO is to understand the sponsor's business needs. This means knowing on a global basis what is technically — the protocol — and financially important to the sponsor. With the majority of pharmaceuticals consumed in the United States, it makes little sense to focus on the rest of the world at the exclusion of the United States. Issues of timely enrollment at home remain the biggest challenge for sponsors, and this fact must be considered when going global in a trial. Country selections outside of the United States should be made with the sponsor's comprehensive goals in mind. Those goals include geographic and ethnic diversity requirements, coupled with time to market and other financial issues. It is also vital to involve the CRO early in the process. The best time for CROs and sponsors to jointly construct their global strategy is when the technical requirements of the protocol are first known, not when the trial is behind schedule. The importance of involving partners in the early stages and giving them the chance to provide input into planning and accept and commit to their responsibilities in making the program a success should not be underestimated. Strong collaboration from the beginning builds commitment between partners, and that commitment yields success.

HLINAK. INVENTIV CLINICAL. The key element for a solid global partnership — the delivery of

Thought Leaders

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ONE OF THE BIGGEST CHALLENGES IS MAINTAINING A DEDICATION TO THE RELATIONSHIP. It takes work and commitment to roles and responsibilities from the top management down to individual project teams.

Deborah Brewer. OMNICARE

clinical services on a global or offshore basis — must be based on common ownership, all or in part, of the CRO and the global delivery platforms. This allows for consistent and controlled services in a more effective way than when the relationship between the domestic CRO and its global partners are mere alliances.

BREWER. OMNICARE. An ongoing commitment between the partner companies to grow the relationship within an organizational and cultural framework will create an environment of success. A focus on creating long-term value for all stakeholders will help strengthen the commitment.

VON RICKENBACH. PAREXEL. The single most important element required in any partnership is genuine commitment. For expectations to be met on both sides, there must be a true intention to form and maintain a global partnership with recognition that there is mutual dependency.

FARINACCI. RESEARCHPOINT. Quite simply, partnerships need leadership. Whether it is a project that is regional, and/or global in nature, a leader must call upon all of his or her experience and skills to manage the global diversity of regulatory requirements, culture, language, and time zones encountered with global development to deliver a high-quality product.

Defining the Relationship Elements

Contracts, on-the-ground research, and teaming up with like-minded partners can help facilitate the trust and communication needed to ensure a successful partnership. Other important factors include implementing corporate liaisons, identifying responsibilities, and outlining expectations and goals.

GRIFFITH. APTUIT. Beyond optimizing communications across the project and assigning a single project manager to orchestrate all of the work globally, another significant consideration is the establishment of a single contract that is enforceable in the United States for all work globally, thereby effectively addressing many intellectual property concerns while working in other regulatory regimes. Additionally, when a pharma or biotech company partners with a contract organization to conduct global work, the sponsor must be involved in project organization as much if not more than the contract organization by having internal corporate liaisons that can rapidly be contacted should issues or obstacles arise. Facilities and teams should be inherently designed for successful global collaboration. When partners are fully engaged on all aspects of a project and organize internally to support active and timely communication, delays at decision-making interfaces that consistently plague traditional drug development can be greatly reduced.

TRIALS IN COUNTRIES WITH VARIOUS OR NO STANDARD OF CARE MUST BE CAREFULLY MANAGED; the major issue is to guarantee the patient's rights to a standard of care and ensure follow up through local public health systems.

Michael Hlinak. INVENTIV CLINICAL

TYSON. CAMPBELL ALLIANCE. There are three keys to establishing the type of trust necessary to ensure an effective global partnership. The first is to clearly define contractual relationships, which include pricing but go beyond pricing and include explicit service-level expectations for both sides of the agreement. The second is to have excellent, on-going communications at both the project and the relationship levels. This allows issues to surface before they jeopardize or break that trust. The third is commitment to the relationship on both sides to ensure that when issues are inevitably identified, both sides are committed to working them out rather than looking outside the partnership.

PAGE. I3. Understanding of the standard of care for each therapeutic area within the region is a huge step toward a successful outcome. This can easily be achieved by using on-the-ground expertise within each region and a flexible global project team model that complements the sponsor's needs. Also helpful is a governance structure that incorporates a shared vision and joint ownership of the goals and overall success of the partnership. To keep partners on the same page at all times, visibility of the future work stream to enable proactive identification of resource needs at the human, geographic and/or technology level works well. This leads to more open communication and innovative vision focusing on solving issues in a collaborative manner.

GEATZ. INCLINIX. Though the idea that a single CRO can serve every need in a global trial looks good on paper, this scenario is rarely the case. Therefore, specialty CROs and other suppliers are needed. It is important that all of these entities focus on the needs of the sponsor as outlined in the protocol and sponsor's business practices. Sponsors must be able to trust that their CROs understand the unique nuances from the regulatory perspective, cultural perspective, and beyond, and will share that information to help drive timely implementation in each country.

HLINAK. INVENTIV CLINICAL. Global presence, solid financial footing, knowledge of each country's particular characteristics, ability to deliver or develop a customized solution spe-

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PROBABLY THE SINGLE MOST IMPORTANT ELEMENT REQUIRED to form a solid partnership revolves around truly understanding the needs of both parties.

Randall Guthrie. XCELIENCE

cific to the client's needs, and demonstrated delivery capabilities — in other words, a good track record — are pivotal.

BREWER. OMNICARE. The partners must have common values as well as shared goals. There must be a good cultural fit with a synergy of corporate visions, missions, and a long-term philosophy for success.

Keeping the Partnership on Track

Like marriages, even partnerships formed with the best intentions are fraught with challenges that continually need to be met and overcome. Lack of commitment, lack of communication, and misunderstandings between parties can put the outcome of many partnerships at severe risk. The vulnerabilities of the relationships can be conquered, however, through planning, consistent communication, keeping models simple, and maintaining realistic expectations.

GRIFFITH. APTUIT. The major challenge that any drug development project faces is misunderstanding of, or gaps in, information. Contractors need a whole-picture perspective of the project and be well connected with the client to ensure success of the overall program. If a project has to be stopped to clarify a component of the project or to have the client make a decision on an issue that was not anticipated, it slows the project down, incurring further cost and risking the rescheduling of production slots. CROs should plan for all aspects of a project, whether they are tasked with every aspect or not. A solid understanding of where a client's project has been and where it's going can help. Having an intimate working knowledge of the entire process and the sponsors' projects makes it easier to make decisions that will maximize time and investment.

TYSON. CAMPBELL ALLIANCE. The risks are many-fold. One risk from the sponsor side includes choosing the wrong CRO; not all CRO affiliates around the globe are equally qualified or committed as expected in the contract. Or the CRO may lose interest in the partnership after it launches and fail to commit the resources necessary. On the CRO side, the sponsor may not truly communicate its partnership relationship to all its staff, or the CRO may find itself in a situation where the sponsor continues to treat the CRO as a vendor rather than as a strategic partner. Some sponsors may jeopardize the partnership by not investing in the communication and management effort necessary to maintain the partnership.

HARTE. ETRIALS. The risks and challenges that inhibit a relationship occur when key decisions are not made, and when surprises occur that impact endpoints, duration of study, and overall team performance and delivery. Whether projects are outsourced or in-sourced, this leads to change orders, missed timelines, and overall failure of delivery. Preparing to face or alleviate these issues can go a long way toward minimizing or avoiding them, especially when using technologies that provide a comprehensive view of clinical-trial data and therefore a means for faster decision-making. Technology is available that can instantly track patients, recognize screen failure causes, locate unproductive or untrained sites, recognize a certain stratum that needs emphasis, and monitor staff member or CRO activity within the system. With today's technologies, especially those integrating the various pieces to simplify the collection, cleaning, and analysis of study data, these data are readily available and enable much greater control of study activity.

GUTHRIE. XCELIENCE. We work in an industry where changes can occur overnight. Priorities shift, development plans change, and let's face it, drug candidates die. Through all this we continue to strive for relationships that can create win-win for all parties in the face of change. From a CRO perspective, maintaining a solid portfolio of different types of relationships is essential. On one end of the spectrum, partnerships are a very sophisticated outsourcing model, but they come with risk. For the CRO, maintaining strong relationships that follow a more simplistic outsourcing model helps mitigate the potential risk associated with the more complex model found in partnerships.

PAGE. I3. There are myriad risks with every partnership, ranging from redundant project team members causing confusion over the responsibility for the tasks within a resource or a region to poor communication pathways that may impact decision making and issue resolution. Challenges such as a poor workflow and inadequate processes can hinder the success of the relationship, as can poor logistics planning for drug supplies, electronic system requirements, and the like. In global projects incorporating affiliates, a weak global leader creates the risk of losing control to the regional entities. Another major problem can occur if there is a lack of understanding of the standard of care in the region in which the trial is to be conducted. Synergy between parties can be undermined by micro-management of the CRO or inflexibility in company processes or company personnel. All of these potential issues can be averted with proper planning, allowing adequate time to develop the execution plan for the project and incorporating certain fail-safe elements, such as ensuring the project team is set up from a global perspective with the sponsor and making sure roles and expectations of performance are discussed and agreed upon up front. Each country needs to be allowed enough time to get up and run-

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THE MAJOR CHALLENGE THAT ANY DRUG DEVELOPMENT PROJECT FACES IS MISUNDERSTANDING OF, OR GAPS IN, INFORMATION. As a contractor, having a whole-picture perspective of the project and being well connected with the client are essential to ensuring success of the overall program.

Michael Griffith. APTUIT

ning, with adequate patient enrollment timelines developed on a country and site recruitment rate, not on a straight-line, everyone-starts-on-day-one rate. A multiphase approach should always be considered when appropriate. Another way to prepare for possible challenges is to leverage the kickoff meeting to plan how the study is to be conducted. During this meeting, develop functional area plans, discuss timelines, deliverables, team building, project-level training regarding indication, standard of care, protocol and processes, and logistics. Other items on the agenda should include development of a global communication pathway with escalation procedures, succession and transition planning, and defining the role of the affiliates on the outsourced project. It's also important to set ground rules. Have an internal leader within the sponsor organization to manage the affiliates and clearly identify the intrinsic company processes, and how these can be effectively employed and managed in the relationship to maximize outcomes.

HLINAK. INVENTIV CLINICAL. The major risk when establishing a global partnership is the lack of understanding of local characteristics and timelines that could affect study start up, such as the time to get protocol approval, drug import, and distribution. As each country has specific regulatory requirements, CROs must have a consistent and comprehensive plan for each country and follow it diligently to succeed. Also, CROs must have a good understanding of local study sites and patient recruitment/retention characteristics to develop strategies to reach the targeted recruitment.

BREWER. OMNICARE. One of the biggest challenges is maintaining a dedication to the relationship. It takes work and commitment to roles and responsibilities from top management down to individual project teams. Having a clear communication and escalation structure will go a long way toward building trust and support.

VON RICKENBACH. PAREXEL. The necessary ingredients of a global partnership are genuine commitment, good communication, and realistic expectations as well as true global access. The absence of any one of these can inhibit success.

FARINACCI. RESEARCHPOINT. I would outline several risks, all of which have their own mitigation approach. First, I would start with the challenge of understanding and accepting cultural differences. This can be overcome through extensive training on cultural differences for the entire team, planning the project schedule around all local holidays, and the use of partners that have deep local/regional knowledge and expertise. Second comes ensuring security of information and speed of communication mechanisms. Establish a secure FTP site for transmission of large volumes of data, test connectivity with investigators and sites before commencing the study, and potentially invest in increased communication bandwidth. Currency fluctuations are definitely a risk that can lead to a situation of there being a currency-related winner or loser. This can be avoided by reviewing appropriate exchange rates to use on a quarterly or semi-annual basis. Conducting a comprehensive feasibility study in each region to identify the prevalence of the disease, review the standard of care, analyze potential subject population against inclusion and exclusion criteria, and determine the availability of investigators can help mitigate enrollment and subject availability challenges before finalizing decisions on global sites.

A Multipartner Partnership

Sourcing methods and models have evolved over the years to adapt to the changing requirements of the sponsors. One size does not fit all anymore, and often sponsors may use several different sources to fill their needs. Being flexible and working with multiple sources at the same time fits the bill these days, but does this new model affect the outcome of partnerships?

THE SINGLE BIGGEST CHALLENGE FOR A CRO IS TO UNDERSTAND THE SPONSOR'S BUSINESS NEEDS. This means knowing, on a global basis, what is technically — the protocol — and financially important to the sponsor.

J. Tobin Geatz. INCLINIX

GRIFFITH. APTUIT. The role of the CRO in the drug development industry has evolved from being a vendor tasked with a single aspect of a project to being an integral driver in the client's overall success across multiple projects. A worthy CRO should aim to provide full-service outsourcing for its clients. The level of trust and strategic partnership that comes with working with clients on a long-term basis across multiple projects allows streamlining of processes and maximizing of investments. Functional outsourcing, in which companies choose multiple providers to handle various aspects of their drug candidate's development, perpetuates the delays in decision-making, loss of critical process and knowledge, and project handoff that has traditionally slowed the drug development process.

TYSON. CAMPBELL ALLIANCE. Partnerships, especially global partnerships, are definitely not for all sponsors. First of all, only a handful of CROs can claim to offer full global capabilities. This immediately reduces the pool of available CROs and limits the sponsor. For a sponsor to even want to approach a global partnership, it needs to have a very clear understanding of its core competencies, what it intends to outsource, the therapeutic areas it

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PARTNERSHIPS, ESPECIALLY GLOBAL PARTNERSHIPS, ARE DEFINITELY NOT FOR ALL SPONSORS. First of all, only a handful of CROs can claim to offer full global capabilities.

Gary Tyson. CAMPBELL ALLIANCE

UNDERSTANDING OF THE STANDARD OF CARE FOR EACH THERAPEUTIC AREA within the region is a huge step toward a successful outcome.

Nigel Page. I3 RESEARCH

intends to work in, the countries it is likely to need to work in, and its future pipeline. Then, the sponsor needs to view outsourcing as a key success factor and empower the outsourcing function to help develop an effective partnership. Most organizations, even large organizations, are not in a position to meet these criteria.

HARTE. ETRIALS. When leveraging global capabilities, the easiest approach is to leverage a global, full-service company. There are companies that have divisions and staff covering most, if not all, of the world to support a global clinical program. Without patients, conducting any clinical program becomes a challenge. Many drug companies need to go global with their study to effectively locate evaluable patients, and the attraction is that many countries have become more sophisticated in participating as active study sites. While this seems to be the easiest approach, an important question that may be raised is: "Are we getting the best available resources for our study's specific needs?" The emergence of niche vendors provides another option for companies to conduct global studies and leverage local knowledge and expertise. Many companies specialize therapeutically or locally by country to offer support services such as clinical monitoring, site selection, or regulatory support. Years ago, this approach would not have been as attractive due to difficulties in managing so many disparate groups. Today, thanks to electronic data collection methods to effectively conduct global clinical studies, managing these many groups has become a more attractive alternative.

PAGE. I3. Different sourcing methods allow the sponsor to be engaged in the day-to-day details of project and portfolio development at different levels. They do not necessarily affect outcomes; rather, they represent choices the sponsor can make. For example, traditional full-service outsourcing is used when either the sponsor lacks the drug-development expertise to run the project because the drug is not in a core therapeutic area or the sponsor needs the additional support of a full team to expedite the development of the drug. The sponsor can be running part of the portfolio internally and outsource part of it so that development is done in parallel. Functional outsourcing is used when the sponsor wants to maintain total control of the drug development and the project but does not have the resources to complete the tasks, or chooses to outsource set services that are not core to the drug development, such as monitoring and data management services.

HLINAK. INVENTIV CLINICAL. A flexible outsourcing model, developed to deliver results according to sponsors' needs, allows a company to invest in priority studies according to its pipeline and financial interest, accelerating the delivery of a product to the market in a more effective cost/benefit manner. Conversely, rigid outsourcing models, as offered by conventional CROs, may be more time and cost-consuming, causing delays in product delivery and compromising companies' marketing strategies.

Global vs. Single Country Partnerships

Global partnerships are a different animal than single country models, and our experts discuss how to deal with the differences between the two.

GRIFFITH. APTUIT. Global partnerships allow drug developers to take advantage of varying cost structures for certain competencies. Various aspects of a project can be completed by experts across the globe simultaneously, ultimately wielding better results and lower costs both in terms of client spend and long-term revenue from products getting into the marketplace more efficiently. Global partnerships also allow drug developers to simultaneously move their products into their end markets. By performing work globally, drug developers gain a physical presence and work with local experts in the regulatory environment of various markets. This is particularly important for smaller biotechnology companies that do not have operations in, or access to, foreign regulatory environments.

TYSON. CAMPBELL ALLIANCE. Global partnerships are inherently more complex. They involve multiple time zones, languages, and assumptions. Most pharmaceutical sponsors will find that many global CROs are not monolithic entities. CROs are more a set of related, but slightly different country-specific entities, each with their own strengths and weaknesses. The global partnership needs to deal with this complexity by ensuring much better communication and issue resolution processes than a simple one-country commitment.

HARTE. ETRIALS. A global partnership is one

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A GLOBAL PARTNERSHIP DIFFERS FROM A SINGLE-COUNTRY COMMITMENT IN MANY WAYS. One of the more significant differences has to do with the multiple regulatory requirements that a sponsor and CRO must deal with in a global environment.

John Farinacci.
RESEARCHPOINT

that provides and supports the clinical needs of a pharmaceutical company to produce, develop, and support its programs, and to leverage the most effective, efficient resources to accomplish the task. To achieve this objective, companies need to be able to locate these resources anywhere in the world to adequately support the partner. The use of technology has had a tremendous impact on the conduct of clinical programs globally. Technology has enabled smaller and mid-size pharmaceutical companies and CROs to compete on a global scale and to leverage local resources to support their studies, all while having the quality study data available to make more informed decisions faster. With technology, larger companies can communicate across the many functional operating areas and global offices of their own network, improving communication and enabling more productive and efficient management. The drug industry has the ability to leverage the world for its clinical trial support, and technology has enabled this change.

PAGE. I3. In a single country partnership the stakeholders are more clearly identified; it is a simpler relationship. In a global partnership the stakeholders may increase with the addition of affiliates and the different structural models employed to accommodate multiple geographic regions. With this elevation of stakeholders and inevitably increased interactions at various levels through the project team, there is more risk to the success of the venture with unintentional miscommunication and incorrect prioritization of local elements ahead of the global requirements. In a global partnership there is a greater need for both partners to maintain a cohesive relationship in: executing the deliverables; reinforcing the clearly defined roles and responsibilities; and preventing deviation from the issues elevation and resolution plan. This can be achieved with a direct and honest communication plan that provides an open platform for both parties to come to the table and address these issues as a partnership.

GEATZ. INCLINIX. Large-scale, single-country clinical studies outside the United States are fairly rare. But the challenges of a global trial are not that much different in nature, only in scale, from ones done right here in the United States. It is important that CROs recognize three things. Clinical trial participation is an unnatural act for a patient. Sponsors are asking a patient to take a strict regimen of an experimental drug that in many cases might be a placebo or the current standard of care. Only an independent principal investigator can enroll a patient; neither sponsors nor CROs can perform that task. Each trial site is an independent operation with numerous competing healthcare and business interests. Basically, deploying globally requires a firm grasp on these issues and selecting sites accordingly. Partnering CROs must do everything within their power to equip these sites with a common platform for data interchange and tools that make the jobs of those working at the sites easier. This is true regardless of where the trial is taking place.

HLINAK. INVENTIV CLINICAL. A global partnership allows sponsor companies to achieve results in a faster, more efficient and less expensive manner, as both the project and budget can be more easily managed by a CRO with global presence and knowledge of local needs.

VON RICKENBACH. PAREXEL. Global partnerships are inherently more complex than a single country commitment. Beyond taking into account issues such as time, distance, and the number of experts who must be involved in a study, global partnerships should reflect even more emphasis on understanding and working together toward shared standards and values.

FARINACCI. RESEARCHPOINT. A global partnership differs from a single-country commitment in many ways. One of the more significant differences has to do with the multiple regulatory requirements that a sponsor and CRO must deal with in a global environment. Local or regional expertise in each targeted region becomes pivotal and must be managed well by the development team to ensure that all critical requirements are met. Another key difference is the coordination required to ensure excellent communication throughout a global partnership. Communication and coordination among any drug development team is crucial, but a study that is global in scope requires an especially intense focus and detailed planning in this area. Frequent conference calls, supplemented by thorough written communication, should be planned to provide as much opportunity as possible to share ideas, provide feedback, and discuss issues. Finally, overall study coordination and program management have unique challenges in a global partnership. The sponsor should ensure it can work with either a global CRO or global network that will provide a single point of contact and accountability.

TYSON. CAMPBELLALLIANCE. For organizations that are unfamiliar with conducting clinical trials in certain countries, the expertise and input of a local CRO is vital for the success of their patient recruitment plans.

GEATZ. INCLINIX. By definition, all patient recruiting worldwide is outsourcing, since only an independent site can actually enroll a patient. CROs must keep in mind that their goals should never conflict with the conduct of the trial at the site. Since there is a serious shortfall in the number of qualified sites, both in the United States and worldwide, that are capable of conducting excellent clinical research, the CRO's role must be additive to the site, not burdensome. Duplicative or unnecessary practices that are demanded of the sites simply exacerbate a historically bad situation. CROs should provide sites global-

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Sound Bites from the Field

CROS NEED CERTAIN CAPABILITIES TO FUNCTION WELL WITHIN A GLOBAL PARTNERSHIP. PHARMAVOICE ASKED CRO LEADERS TO IDENTIFY WHAT SOME OF THOSE CAPABILITIES INCLUDE.

SEAN L. HART is General Manager, Client Services at United BioSource Corp., Bethesda, Md., a global pharmaceutical services organization that helps emerging and established life-sciences companies develop and commercialize medical products. For more information, visit unitedbiosource.com.

"The global environment mandates that pharmaceutical services organizations like UBC stay current with evolving requirements, paying attention to both big-picture decisions and detailed planning, from strategic regulatory decisions to technology choices to risk minimization and safety issues.

It is imperative to trouble-shoot and develop solutions before launching a program — considering target countries, language and translation implications, technology pros and cons.

Understanding cultural nuances, for example, is critical to establish clear processes and inter-personal expectations. Global regulatory knowledge and flexibility are necessary to plan effective programs. And you must be ready to respond to country-specific changes. In our 24-hour world, you also need electronic capability, as well as a multilingual staff with local language capabilities. Also important are SOPs to ensure that core processes are followed, clear directives for operational staff about services and timelines, and a governance team overseeing metrics and deliverables. In addition, senior leadership support is critical to overcome any implementation challenges. Finally, we believe strongly that regular face-to-face meetings help create a strong team environment."

JOHN HUTCHIN is a Senior ePRO Consultant at CRF Inc., Waltham, Mass., a global, enterprise data capture partner to the pharmaceutical industry. For more information, visit crfhealth.com.

"Companies embarking on a global partnership need to find a way to devise a win-win arrangement for both participants, otherwise the enthusiasm for the partnership will wane quickly. Beyond this, it helps to have a legal department well-versed in international law and a corporatewide appreciation of cultural differences, business practices and customs.

To keep communication lines open, it's important to have (or develop) distributed expertise and personnel backups to accommodate time zone differences.

Also, it's important to maintain flexibility when scheduling meetings across those time zones and be willing to adapt your internal SOPs to benefit the partnership arrangement.

Finally, try to achieve global relevance while maintaining local sensitivity — that is, remember your core values and don't get too big for your britches."

LEE JONES is CEO of Essential Group Inc., Gurnee, Ill., a provider of patient recruitment and contract research organization services to pharmaceutical and biotech companies to achieve clinical trial outcomes with control over a timeline and budget. For more information visit essentialgroupinc.com.

"CROs need to provide the scope of services required to meet local and global regulatory guidelines to ensure any generated data can be used in a global manner. This requires providing best-in-class services to meet the specific needs of a clinical study and that may not always come from intramural resources. The services range from using local monitors who know the language, customs, and regulations, to using biometrics that maybe located elsewhere in the world, but that can provide the experienced analytical insight expected of the regulators and sponsor management. The focus must be on quality and drug development experience, not primarily low cost, which too often is the case."

JIM LANGFORD is VP of Channel Sales and Partnerships at ClinPhone, Nottingham, U.K., a provider of a range of clinical technology solutions. For more information, visit clinphone.com.

"Capabilities required for success in a global partnership include: the ability to localize; a solid foundation and infrastructure built on experience in clinical trials processes; and robust and flexible technologies.

Partnerships are vital as each member provides unique perspectives and expertise. Whether it's language, culture or even technological capabilities, localization is critical for a clinical trial to run smoothly and to address any variables that could potentially compromise the results are minimal.

There may be inefficiencies or flaws in local processes that are detrimental, so a partnership must possess a foundation and infrastructure in conducting trials around the world. Experiential knowledge that can be coupled with the localization principle is invaluable.

Technology that optimizes efficiencies and is scalable is critical. Technology extends the global reach of partnerships and increases time and cost savings, as well as facilitates better collaboration across time zones."

KELVIN LOGAN, PH.D., is President of INC Research, Europe, a therapeutically focused contract research organization with headquarters in Raleigh, N.C. For more information, visit incresearch.com.

"CROs need a strong global infrastructure to apply the same high standards of good clinical practice in the major patient recruitment regions of the world: North America, Western and Eastern Europe, India, Latin America, and China. This requires a consistent approach to quality and the adherence to global standard operating procedures. The use of uniform IT platforms and trial management systems are equally important while managing the different regulatory, cultural, and language requirements of each country."

RONNY SCHNEL is Executive Director, Business Development and Client Services, at Criterium Inc., Saratoga Springs, N.Y., a global, full-service CRO. For more information, visit criteriuminc.com.

"In the traditional sponsor/CRO business model the formula is: strategy multiplied by execution equals results. In a global environment, it's important that trust is added to the relationship equation. The result of any clinical program can be diminished by a low-trust tax or enhanced by a high-trust dividend. Trust is not a soft, nice-to-have quality. Trust is hard, real, and quantifiable. Trust can measurably impact the speed and cost of a global development program. Trust is built on integrity, strength of character, and competence of the team members. Thus the key leadership competency of the new global economy is to develop solid and trusted relationships with all stakeholders — sponsors, suppliers, and other contributors — that may impact the success of global study. Everyone is interconnected. We learn to interrelate and connect by improving communications, developing respect and appreciation for each other, and understanding team members — no matter where in the world they sit."

RICH VACHAL is Director of Operations, XTrials Research Services, Somerset, N.J., a full-service contract research organization with international resources dedicated to the planning, execution, and analysis of Phase I through Phase IV clinical trials for drugs, biologics, and medical devices. For more information, visit industrydynamics.com.

"Establishing global partnerships can be an effective approach to extending clinical operations and development programs to overseas patient populations. For both sponsors and CROs alike, it can provide efficient entry to the enhanced patient accrual capabilities and attractive per patient unit costs available in foreign venues. But it can also present unique challenges regarding in-country medical practices, regulatory environments, and partner business values, standards, and procedures. Identifying a trustworthy partner and negotiating an equitable, well-defined relationship is key. But given this partner will provide the on-site eyes and ears, assuring clinical protocol compliance and supplying IP shipment and ready-to-enroll decision support information, sponsors need to be able to not only trust, but verify that their requirements are met and standards are consistently applied. Leveraging an agile, Web-based e-clinical system to maximize international collaboration and process transparency will be the difference between the partnership being a star or a bust."

JOHN VANN is Executive VP, Americas, in the Bristol, Tenn., office of Chiltern International Inc., a global contract research organization. For more information, visit chiltern.com.

"Any successful partnership — global or otherwise — is built on trust. Trust implies transparency. Transparency comes when working in a cooperative environment with a common understanding of the task at hand while sharing a common goal.

At the beginning of every bid process, the sponsor reviews the CRO's structure, processes, teams, and experience to ascertain that all the resources needed to conduct the study to a positive outcome, on time and within budget, are present. Leading CROs are focused to make sure they have all these resources in place.

What is not stated, as a requirement, in the RFP is that the client will trust the CRO and vice versa, which implies it is an assumed attribute. But while good working relationships are always desired, they must be developed, and mutual trust must be earned. Too often the temptation is to focus only on processes, but it is the added investment of time in the relationship that creates the solid foundation and the successful conclusion of projects.

The global perspective simply enlarges the challenge and the opportunity, for both the sponsor and the CRO. In my opinion, the CRO must be capable of, and responsible for, driving the effort to develop a relationship that achieves the common goal of meeting a sponsor's needs that are as yet unmet. From my experience, after this is done everything else falls into place whether the study is conducted domestically or globally.

A GLOBAL PARTNERSHIP IS ONE THAT PROVIDES AND SUPPORTS THE CLINICAL NEEDS OF A COMPANY to produce, develop, and support its programs and to leverage the most effective, efficient resources to accomplish the task.

Michael Harte. ETRIALS

ly with useful technologies and services that lessen the sites' workloads. Accomplishing this task requires a fundamental understanding of how the business of clinical research is conducted on a country-by-country and a site-by-site level. This understanding of sites must then be married to the scientific and business interests of the sponsor. Plain and simple: a CRO's role is to make the sites' and sponsors' interests coalesce, in the United States or worldwide.

HLINAK. INVENTIV CLINICAL. A global presence and the knowledge of local recruitment characteristics, such as regulatory requirements, local culture for clinical trials, and each country's health systems are the keys to predict enrollment rates and develop recruitment plans. The role of outsourcing is to identify and manage these issues in each particular country. ✦

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