BY TAREN GROM

CROs: MISSION possible

Cost, time, capability, and **risk** all impact the CRO-sponsor relationship. By going **back to basics** and concentrating on the fundamentals of outsourcing, the industry can develop strategies that **address these complexities**, benefiting both CROs and sponsors.


Dr. Candace Kendle

We are all working to get through the development process and **TO LAUNCH A PRODUCT AS QUICKLY AS POSSIBLE**. A partnership effort can result in best strategies for both the CRO and the sponsor.

MISSION ANALYSTS ...

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ERIC F. HAYASHI. VP, corporate development, Radiant Research, Kirkland, Wash.; Radiant Research is a privately owned company that owns and operates more than 40 clinical-research sites that conduct Phase I-IV clinical trials for pharmaceutical, biotechnology, medical device, and contract research organizations

LORI KAISER. Director of marketing, TherImmune Research Corp., Gaithersburg, Md.; TherImmune Research is a fully integrated CRO that provides drug-development services to the pharmaceutical and biotechnology industries, specializing in providing complete IND packages and delivering high-quality non-clinical and clinical studies and analytical, infectious disease, immunology, and pathology services to its clients

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VINCENT LAGROTTERIA. Executive director of sales and marketing, Medifacts International, Rockville, Md.; Medifacts International is a leader in the global management of cardio-vascular, renal, pulmonary, and CNS clinical-development programs for the pharmaceutical, biotechnology, and medical-device industries

COLIN MILLER, PH.D. VP, business

Companies decide to outsource to create and then capture value, the mission being to find equitable solutions that benefit each party without further complicating the relationship. However, according to industry experts, the value to the drug company has been declining at the same time profitability for the CRO has been eroding.

Despite best efforts by pharmaceutical sponsors and outsourcing providers it is inevitable that changes will occur, no matter how accurately the specifications at the beginning of a project are defined. Sponsors may redefine their needs, unforeseen delays may jeopardize the timeline, new services may impact the budget, and personnel turnover may affect communication and decision making. Managing these changes, and minimizing disruption to the project, becomes the mission to building and maintaining successful relationships.

To compete effectively in today's business environment, companies rely on these strategic alliances to link their resources with those of other corporations, to give them access to core competencies not in their domain. However, industry statistics reveal that fewer than 50% of the alliances between large and small firms survive four years. The mission, therefore, is to develop management tools and metrics to increase the value of the alliance.

Silos between various functional teams must come down in order to industrialize the traditional laboratory-based system of drug discovery and development, say industry experts. In such an environment, research managers will be more concerned than ever about efficient information sharing and effective use of time and resources and parallel development. The outsourcing environment must become one that is less hampered by rigid definitions of responsibility; one that seeks to encourage more efficient flows of data, information, and knowledge; and one that demands more productive allocation of resources.

The challenges are many. But through an analysis of the components that provide the architecture of the sponsor-CRO relationship, by drilling down to find solutions that benefit each party, the mission of accelerating drug development in a timely and cost-effective means is more than just possible. Industry experts stress developing these solutions is imperative to meeting the various demands of today's business environment and filling the pipeline for the future.

The ideal client relationship is to meet with various levels of the client's organization regularly, **TO RECEIVE FEEDBACK FROM ALL LEVELS.** Service providers need to hear from every level within an organization.


Josef H. von Rickenbach

development, Bio-Imaging Technologies Inc., Newtown, Pa.; Bio-Imaging is an Image Core Lab, which is dedicated to the management of medical images that support the product-development process of the pharmaceutical, biotechnology, and medical-device industries

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MICHAEL ROSENBERG, M.D. CEO, Health Decisions Inc., Chapel Hill, N.C.; Health Decisions is a provider of worldwide comprehensive clinical-research services, including new processes, software, and use of the Internet, which reduce the time required for clinical evaluation and registration of drugs and devices to pharmaceutical, government, and non-profit organizations

CHRISTOPHER SPEH. President, Resource Solutions Inc., Research Triangle Park, N.C.; Resource Solutions is a specialty CRO providing quality trials management, clinical monitoring, and QA services encompassing broad-based clinical R&D support to pharmaceutical, biotechnology, and bio–pharmaceutical sponsors in the fields of oncology, pain, and neuroscience

BILL TAAFFE. President and CEO, North American Operations, Icon Clinical Research, Philadelphia; Icon offers a variety of Phase I to IV support services, which can be offered on a stand-alone basis, or as part of full-service clinical-research management and has offices in North America, Europe, the Pacific Rim, Argentina, and Israel capable of conducting clinical-research studies ranging from small local trials to large global programs in a wide range of therapeutic areas

JOHN R. VOGEL, PH.D. Consultant, John R. Vogel Associates Inc., Wailea, Hawaii; John R. Vogel Associates is a drug-development consultancy that works with pharmaceutical companies and pharmaceutical service providers in the U.S., Europe, and Asia to enhance results achieved through outsourcing

JOSEF H. VON RICKENBACH. Chairman and CEO, Parexel International, Waltham, Mass.; Parexel is one of the largest contract pharmaceutical outsourcing organizations in the world, providing a broad range of knowledge-based contract research, medical marketing, and consulting services to the worldwide pharmaceutical, biotechnology, and medical-device industries

STEVE ZISSON. Managing editor, CenterWatch, Boston; CenterWatch is a publishing and information services company used by patients, pharmaceutical, biotechnology, medical-device companies, CROs, and research centers

COST analysis

VOGEL. There is pressure toward the commoditization of CRO services. The pharmaceutical industry recognizes that it is spending increasing amounts of money on CRO services. And as the amount of these monies increases, there's increased focus on cost. The pharmaceutical industry has begun to centralize the purchasing of its CRO services through contract-management groups. One of the mandates of these groups is to look at potential cost savings. Both sponsors and CROs would do well to distinguish between value and price and focus more on value than just on price. There is an overall trend by the pharmaceutical industry to try to pull the cost of CRO services down.

TAAFFE. The interactions/relationships between sponsors and CROs have changed considerably over the past few years. In an effort to streamline and formalize the process most sponsors now require CROs to conduct all business aspects of a study or program with an outsourcing/procurement department. In the past, all matters were discussed with the operations director or medical director. This new initiative has introduced CROs to a formal RFP process with detailed bid grids and elaborative bid-defense meetings. This has brought order to what was a very loose process. But in many cases the system is very time consuming and costly to both parties. The focus on cost considerations and cost comparisons can reach excessive levels of finesse and often contribute to, instead of, reduce development costs. We have probably gone too far in trying to impose controls. Because clinical research is a "fuzzy" business it does not lend itself to unit-price costing. Also, there are no standard definitions of the units used. Consequently it is almost impossible for a sponsor to compare bids on a task-by-task basis. The bid grids never match a CRO's costing system and the CRO will then artificially break down its customary calculation amounts into the desired cost items. Because of this exercise numerous assumptions have to accompany every bid.

CROs should propose solutions to bottlenecks based on experience rather than wait for the sponsor to develop the answers independently. The CRO needs to be proactive and be a partner in that particular program and come forward with ways to streamline the project, rather than wait for us, the sponsor, to fall. **THE CROS NEED TO GET OVER THE PERCEPTION THAT THE SPONSOR IS ALWAYS RIGHT, BECAUSE WE ARE NOT.**

KENDLE. Some sponsors really do understand this is not a commodity business, we are in the research and development business. And, by definition, the response of the patient to the drug is unknown. The need in the marketplace is unknown. The competitive space is pretty gray. From entry into man to the marketed product also is a very gray area. We are all working to get through the development process and to launch a product as quickly as possible. A partnership effort can result in best strategies for both the CRO and the sponsor.

MILLER. There are three dynamic factors in a clinical trial — time, quality, and cost — of which we have to choose two. Enlightened clients appreciate that dynamic and appreciate that quality comes at a cost. That makes a big difference in terms of team building and putting a relationship together.

MINOR. Developing economical, flexible systems and having skilled employees able to interface with myriad sponsor programs is crucial. Every sponsor has their own unique way of doing things.

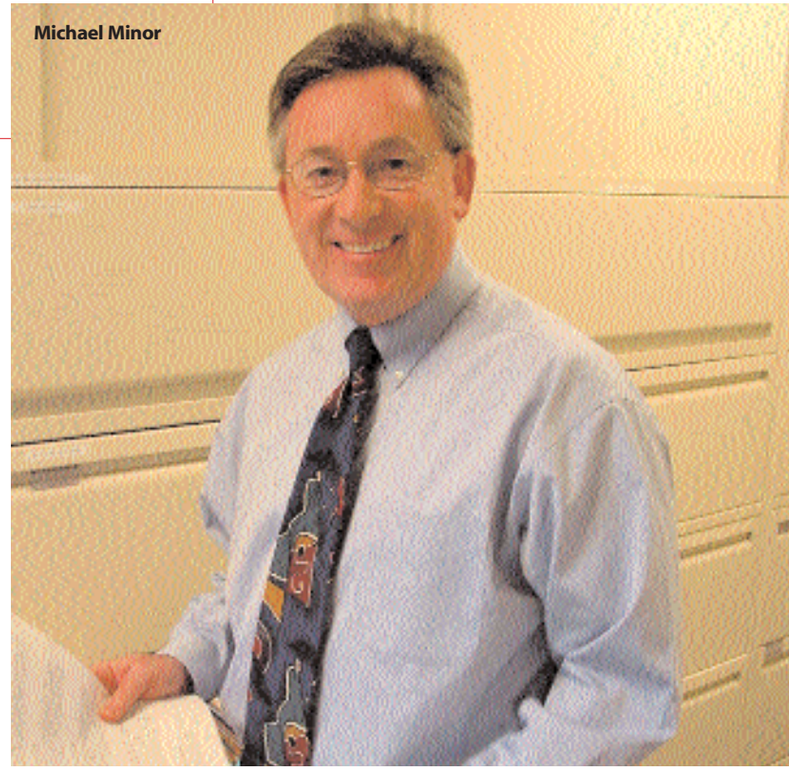
CHILDERS. There has to be high quality in terms of science and systems, there has to be a timeliness component, a communication quotient, and there has to be profitability. A company has to be profitable, that's not to say overly profitable, but we have to be profitable to be healthy. We have to negotiate contracts that are favorable for both sides. We can't just take work because we need work for revenue and not be profitable. Profitability has to be there. It's not a dirty word, it has to support both sides.

TIME analysis

MILLER. Client expectations and timelines are two big challenges. Many new clients do not appreciate the components of medical imaging and how much up-front work needs to be done to get the site up and ready. Often, we are brought in too late to get ahead of the front end of a clinical trial or we are brought in to do so-called salvage operations or obtain images from a trial that already has been completed.

NELSON. Managing sponsor expectations is vital, CROs don't push back. We'll come up with a very optimistic timeline, especially for things like patient recruitment. The CRO should push back and tell us we're being overly optimistic. This would help win the trust of sponsors in terms of estimating project time, cost, and quality.

KAISER. CROs are finding it more and more difficult to meet the timelines for clients due to capacity issues. Whether we partner with large biotech and pharma companies with multiple parallel track drugs in their pipelines or small biotech companies that need full drug-development capabilities, being able to meet their time-sensitive needs may become a challenge. We are continually looking at ways to expand our capacity.


Michael Minor

LAGROTTERIA. A big challenge facing our industry is the lead time needed to build a relationship and gain an understanding of a sponsor's needs for a clinical study or consulting service. We typically get called in pretty late in the game. In our relationships that we've been able to develop into a partnership, we are able to get in early and discuss different programs that are going on in the future. That's extremely helpful in terms of resourcing, staffing, and gaining a better understanding of the client's culture.

SPEH. Management at pharma sets timelines for submissions. These objectives often are established with Wall Street in mind. The way to meet these objectives is to ensure that the company has products completing the FDA-approval process on a fairly regular, and ideally accelerated basis. Because drug development is such a lengthy process the end points are established very early on. The difficulty comes into play in deriving a protocol that is going to satisfy the needs of the pharmaceutical company and satisfy the agency requirements — those interim steps take time. There's a lot of jockeying that goes on to ensure that the protocol that ultimately sees the light of day is going to stand up to FDA scrutiny and is going to achieve what the company is seeking in the package insert. There's a lot of very intense activity that takes place between the time the dates are set and the time that the studies actually get under way. Start dates often slip because the pharma company hasn't gotten FDA approval, or perhaps it's struggling with other issues, but the back end typically remains firm. Pharma companies find their teams are as strapped for time at startup as CROs. It's not that the companies are trying to penalize the CROs, it's just a very complex process to move ideas from the preclinical design stage into an IND and then ultimately into studies. Clearly, the longer we have to plan and work with a sponsor to identify the best locations for sites and monitors, the best combination of experience and skills, the better that's going to be for the sponsor. Sometimes the timing just isn't there. On the service side, we have to respect that — the process is complex and we have to be prepared to respond.

VON RICKENBACH. Due to client timelines, we often have a very short timeframe to assemble a client proposal for a particular project. We suggest to clients two stages of competition for a project. The first relates to the design of the project allowing creative and professional thinking to take its course. The final stage focuses on the construction of the project.

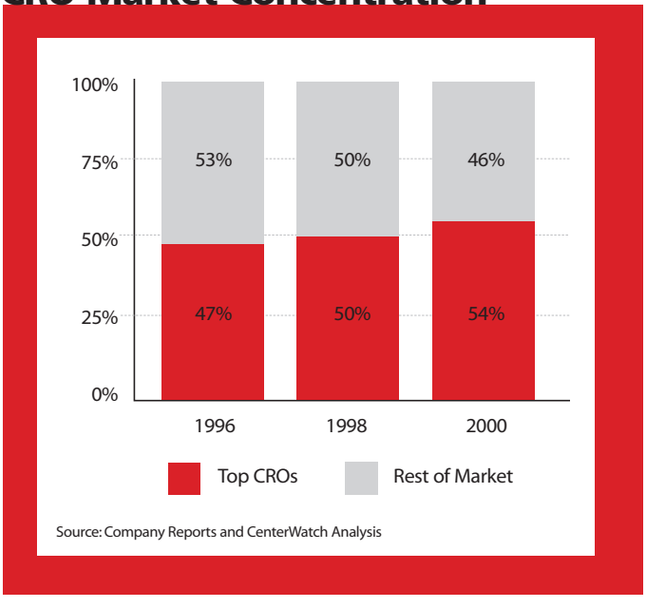

Dr. Colin Miller

CAPABILITY analysis

MINOR. It seems the biggest lament when we discuss the outcome of an outsourced project with a team is that the CRO "didn't get it." A part of that is our own problem. As a sponsor we need to give the CRO the right information and succinct directions as to what we're looking for.

> The ideal relationship is where sponsors treats us as an extension of their operations. That has to work from the contract all the way down to the project-management level with the appreciation that we are **ALL PROFESSIONALS DOING A JOB**.

CRO Market Concentration



Source: Company Reports and CenterWatch Analysis

AVELLONE. The CRO can't be everything. The tasks of the CRO, which can involve every aspect of clinical trials short of patient recruitment, are complex. The CROs' challenge going forward is to differentiate themselves. Even as the leaders in the industry grew up, they often grew out of different core competencies. Some differentiated themselves on the basis of having the ability to enter foreign countries on behalf of trial sponsors, some were good at data collection and analysis. As the industry matures, the larger ones increasingly will find it difficult to differentiate themselves. In the future, one way to differentiate themselves will be to take on the role of centralized, coordinated patient recruitment, with us, or on their own. Either way, specialized patient recruitment is going to have to be a big part of solving the total riddle for pharma going forward.

KENDLE. The hallmark is around process improvement. We are maturing as an industry in the buying and selling of services, but we have a long way to go with regard to the shaping of the services. We are in a highly regulated environment, with a base of products that is changing rapidly due to advancements in science. These advancements are continuing to shape the products and services CROs can offer.

CHILDERS. Pharmaceutical and biotech companies don't always realize that there is a tremendous amount of talent and expertise within CRO companies and they need to continue to seek out this expertise. The advantage to biotech companies and virtual companies is that they get access to a large array of scientists with different expertise. It's very hard for them to duplicate this same expertise in house. We allow our clients to spend their money on the


Lori Kaiser

development of a potentially successful drug, rather than on the bricks and mortar. By using a CRO, companies get a whole onslaught of different talent and even if they need them 5% of the time, they have them at their disposal to help move their compounds through the pipeline quickly.

VOGEL. From the CROs' point of view, they have to be more selective in what they take on. They need to recognize that some projects may not be a good fit for them. In the long run, they would earn the sponsor's respect by declining projects that aren't a good fit for their expertise. Some projects fail simply because, in part, the provider may not have been a good choice for that particular project. Also, providers need to clarify exactly what the sponsor's expectations are. There is a tendency to try to be reassuring and accommodating to a prospective client. The problem is this can often mask exactly what the sponsor is expecting of the provider. Sponsors tend to focus on process more than outcome because they believe that the process is the short-term approach to achieving the desired outcome. CROs, and most service providers, tend to focus on the end result. The discrepancy occurs when the sponsor is expecting the CRO to follow a particular set of procedures, which may not be similar to those that the CRO typically uses and may not be the most effective approach for the CRO. When CROs choose to follow their own procedures, sponsors can become alarmed because they notice that there's a discrepancy between what they expected and what they are observing. Sponsor then try to impose process on the CROs. There needs to be much more open and frank conversations about whether sponsors are going to be focused on process or whether they clearly can define the outcome and buy into the CRO using its own process.

ROSENBERG. There is an increasing requirement to bring expertise to the process, rather than just turning the crank. The CRO needs to be able to bring some capability to the project that the sponsor doesn't have. There are two elements to that. One is the technology component. Secondly, currently the most common model, especially among big pharma, is to use outsourcing as a rent-a-body approach. But increasingly, what companies are looking for is an organization that can offer the overall goal of improving the efficiency of the development process.

> The best way to forge long-term relationships is by listening to and understanding the client and producing timely, quality-driven work. To be effective, **ALL PARTIES HAVE TO BE ON THE SAME PATH.**

KAISER. We want to understand the client's long-term goals. By understanding their goals, we can help them plan for the future. This may mean working with a client to create a strategic drug-development plan as well as providing them with all of the integrated services to implement the plan. The best way to forge long-term relationships is by listening to and understanding the client and producing timely, quality-driven work. To be effective, all parties have to be on the same path.

PERSONNEL analysis

MINOR. Sometimes the teams that are presented at the beginning of a project change dynamically over time. Being flexible enough and having people with a good book of skills to be able to plug and play is difficult. Turnover is too high. Along with that is having the right cohort of workers ready to do the job when the sponsor requests them. A misperception on the sponsor's part is thinking that CROs have a workforce that is ready to go at the snap of the fingers and that they can be there forever.

VOGEL. CROs need to focus on ensuring greater stability in their organizations. There's a lot of mobility among drug-development personnel — at sponsors and CROs. But it's particularly alarming to sponsors when they see turnover in the technical staff at a provider. In my discussions, sponsors continually ask how they can avoid turnover with providers. While turnover can't be totally eliminated, the problem could be minimized if, one, the provider brought the sponsor into the picture earlier. That is to say, advise the sponsor of pending changes and perhaps offer the sponsor a selection of

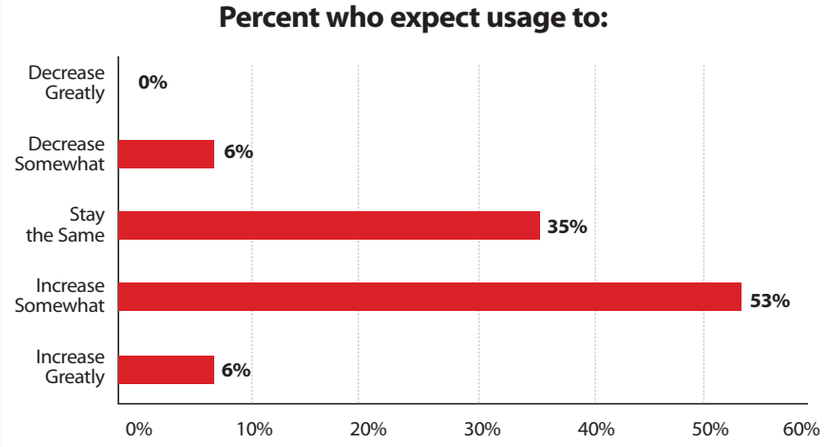

Dr. Joseph Avellone

> **THE CROS' CHALLENGE GOING FORWARD IS TO DIFFERENTIATE THEMSELVES.** In the future, one way to differentiate themselves will be to take on the role of centralized, coordinated patient recruitment, with us, or on their own. Either way, specialized patient recruitment is going to have to be a big part of solving the total riddle for pharma going forward.

potential replacements for a particular staff member. The present practice seems to result in the sponsor being the last to know about a change in staffing. That just adds insult to injury. That's part of an even larger problem, in that there appears to be great reluctance on the part of CROs to disclose problems to a sponsor early on. This results in the sponsor not being able to suggest, or buy into, alternative solutions. And certainly, this weakens the amount of trust between the two organizations. CROs don't tell the sponsor they have resource problems, and often they will choose what they think is the best selection of things to advance and which things to put on a slower track. That often is not parallel to what the sponsor's choice would have been. Or, the sponsor finds out about a problem at the last moment and doesn't understand what happened, and this erodes trust in the relationship.

SPEH. At the moment, the biggest challenge is timing: finding very experienced, very competent professionals when our pharmaceutical sponsors need them. Our sponsors expect us to bring a high level of experience when we take on a study for them. Because study needs usually do not develop in smooth cycles, we find it's a challenge to continue to be able to identify people who have a high level of experience at just the right time. There are a couple of reasons for this. A major factor is simply the number of studies being put out to bid. There was a period when a number of programs were pulled as pharmaceutical sponsors were going through consolidation. In the past 12 to 18 months, many of these programs have come out and hit the street. That has put a lot of pressure on CROs simply to identify and bring staffs into play who are capable of handling this bolus of work. As the market expands, so too does the demand. For our particular sector, when multiple projects emerge at the same time, that inevitably will strain resources of the most experienced monitors.

Sponsor CRO Usage in the Next Five Years



Source: CenterWatch Survey of Pharmaceutical Companies, 2000

TACTICAL analysis

VOGEL. One of the drivers of cost in drug-development outsourcing is efficiency. Drug-development outsourcing is highly inefficient and both sponsors and providers share the blame in terms of that inefficiency. On the sponsor side, sponsors tend to be very tactical in their outsourcing and use CROs as a last-minute, finger-in-the-dike solution to a shortfall in resources. Sponsors ought to be more strategic and decide what are the core competencies that they want to retain in house and what are the services that CROs could provide as well, or better. Sponsors need to include outsourcing in their clinical-development plan so that they anticipate the need of a CRO several months prior to the actual initiation of the project. Typically there is a last-minute rush to find a CRO because a project is starting imminently. That tactical approach leads to misunderstandings and other relationship problems. The tactical rather than the strategic approach is the first mistake sponsors make. The second is that sponsors don't put as much time and effort into designing a relationship with the CRO as they do in designing the deal. I think sponsors believe if they get all the terms in the contract, that will ensure that the project will go smoothly. It's the relationship between the

Vincent Lagrotteria

I VIEW OUTSOURCING AS PARTNERING VERSUS CONTRACTING, which is like purchasing. In outsourcing, we're looking for ways to help each other get what we want more efficiently and effectively. Contracting or purchasing is more tactical — every single time we have to recreate the wheel. Products or services are viewed more like commodities. Outsourcing is more strategic in nature and allows everyone to take a longer-term view.


Dr. Alfred Childers

There has to be high quality in terms of science and systems, there has to be a timeliness component, a communication quotient, and there has to be profitability. **WE HAVE TO NEGOTIATE CONTRACTS THAT ARE FAVORABLE FOR BOTH SIDES.** Profitability has to be there. It's not a dirty word, it has to support both sides.

two teams, understanding of roles and responsibilities, having a clear communication plan, an understanding of how problems will be resolved, and what metrics will be used to evaluate the progress of the project, that are the tools for success. There isn't enough emphasis placed on those.

VON RICKENBACH. Parexel is working with many large pharma companies, as well as the emerging biotech companies. We share their challenges. One challenge is the significant number of patent expirations facing many of our large clients. This places enormous pressure on these drug companies. Compounding this pressure is the challenge of ushering new blockbusters rapidly into the drug-development pipeline. This may result in decision making weighted more toward the short term than long term in areas such as portfolio prioritization, project cancellations, etc.

KENDLE. The CRO industry is a maturing marketplace. Pharmaceutical companies and the larger biotech companies, as buyers, are more sophisticated. They are looking for strategic approaches. And, as a group of CROs, we are more sophisticated sellers. We are working strategically to develop partnerships, services, and a business mix that the customer wants in the right framework of pricing and timing. All of these factors point to a more mature marketplace compared with even five years ago.

MINOR. I don't think sponsors really think about the burden they have in developing working relationships with CROs. Projects are routinely looked at as tactical rather than as strategic endeavors. Status reporting, financial reporting, and developing communication information exchanges are a burden to the sponsor to create. If a company doesn't continue to use the resources it has managed for a project, it loses them. There's not a lot of strategy or thought about what's the next project a company can roll a CRO to, especially in companies that are compartmentalized and therapeutically aligned, since there is limited exchange outside the compartments. It's incumbent upon the CRO to be able to present those opportunities back to the sponsor, and then use that leverage to continue utilizing a trained staff for repeated work. It's really incumbent on the CRO to know the client.

VOGEL. The problem is that, to a great extent, drug development is steered by clinical teams. And the clinical teams tend to exist as their own therapeutic silos — some have greater insights about outsourcing than others. Because work is being done through these teams, sponsors tend to be individually project-oriented — or have a transactional orientation. They are doing one-offs, rather than looking at long-term goals. Sponsors are not developing relationships that anticipate a series of needs or events that occur over a course of many years. Outsourcing between pharma and CROs tends to be very transactional.

HAYASHI. Study sponsors need to develop a more sophisticated approach to selecting investigative sites based on more sophisticated relational databases, rigorous metrics, and performance heuristics. DataEdge has found that in an average clinical trial about one-third of the sites enroll almost zero patients, one-third of the sites enroll about 20% of the patients, and the top-third, which they call the "super sites," enroll 80% of the patients. Sponsors need to be more focused on the quality of the site and the ability of the site rather than the quantity of sites. It's common knowledge that 80% of projects fail to meet their originally targeted enrollment deadlines and clearly the cost of this lost time is enormous. Two culprits — both solvable — are a broken site-selection process and misguided investments, or lack thereof, in participant recruitment activities. Part of the reason a more advanced study-conduct methodology doesn't exist is that, until now, there have been no site management organizations with the operational ability to be utilized as they were originally conceived; and specialized patient-recruitment companies are just now emerging successfully.

LEVERAGE analysis

MINOR. Most of the major CROs will tell us what percentage of their revenue is generated from a single source, or from different sources. There's a relatively small subset of sponsors that big CROs deal with routinely. That's a good thing, because CROs recognize that they have core competencies that they know plug in well with Pharmacia, AstraZeneca, or Pfizer for particular areas. They don't want to spread thin their expertise or experience by delving into other areas, where it can take a long time to achieve that same expertise and success.

CHILDERS. Whether intentional or unintentional, larger clients tend to receive additional benefits from outsourcing. Some clients tend to outsource large programs or multiple projects that, over time, allow contractors the ability to create a relationship and share more knowledge across the lines of communication. Individual onesy-twosy type testing does not always allow time to cultivate a strong relationship. Hence, they will get the expert science and correct data, but they are not getting the time and attention from the consulting side because there's just not enough revenue to provide for that.

NELSON. CROs need to speak up if an inefficiency is identified. We have a huge number of processes that we like our partners to adhere to. But if we are behind the curve and there's an opportunity to seize a new process we'd like to know about it. CROs need to show an ROI of bottleneck solutions in terms of real dollars, not opportunity costs. If a CRO can demonstrate to us what the real value of change would be, what it would really cost us — and that's usually in time — that has real value, especially for the marketing

folks, who need rapid access to the information from our studies to promote products and beat the competition.

VON RICKENBACH. The ideal client relationship is to meet with various levels of the client's organization regularly, to receive feedback from all levels. Sometimes client management is very happy with the completed work, but at another level, managers aren't as satisfied. Service providers need to hear from every level within an organization. At the same time, these meetings can be used for prospective thinking in terms of new projects or implementing advanced technologies. Fortunately, this process is beginning to occur with increasing frequency. Additionally, we can provide input to support clients in innovative ways through the tools, approaches, methodologies, and technologies that we have available to us. In a small-client environment, such as emerging biotech companies, the needs are quite different. Very often, a small or young company may not know what it needs to know to be successful or the questions it should be asking.

MINOR. CROs should propose solutions to bottlenecks based on experience rather than wait for the sponsor to develop the answers independently. The CRO needs to be proactive and be a partner in that particular program and come forward with ways to streamline the project, rather than wait for us, the sponsor, to fall. The CROs need to get over the perception that the sponsor is always right, because we are not. CROs need to leverage successful endeavors across sponsor divisions to effectively utilize trained staff for repeat performances. This basically reduces costs by reducing the training burden.

VON RICKENBACH. An important aspect is the development strategy. Drug development is complex. Many small companies don't have experienced in-house staff or institutional knowledge about what to do, how to approach the FDA, how to interface with foreign agencies, how to liaise with medical centers, how to develop opinion leaders, or communicate with patient groups or reimbursement players. If a client company fails to coordinate these activities at the start of a project, it may delay or miss crucial milestones as the project unfolds. This forces the company to re-do certain portions of the project and incur costly delays.

NELSON. There needs to be a seamless team optimum approach with no redundant resources. There are a lot of redundancies in projects on the sponsor side that duplicate resources on the vendor side. When we outsource, there are a tremendous amount of resources applied to review and accept the deliverables when they come in. That's not necessary. If everybody understands what the objectives are, and is properly incentivized to get the project done and run it on schedule, that will help foster a team and we won't need redundant resources.

MILLER. The ideal relationship is where the sponsor treats us as an extension of their operations. That has to work from the contract all the way down to the project-management level with the appreciation that we are all professionals doing a job. The trust that's built up in this type of environment enables us to give them the best possible outcome, not just from a financial standpoint, but from a quality aspect. If there's trust, the client relies on us to get the job done without micromanaging, but appropriate reporting and checks need to be built in.

STAKEHOLDER analysis

VOGEL. Outsourcing represents a considerable change in the role that in-house pharma people play. These are highly technical people, who may lack the skills to manage a relationship with an outsourcing provider. They were hired to perform technical tasks, not manage business relationships. Outsourcing represents a real change in these people's job descriptions. It's only recently that the pharmaceutical industry has begun to support in-house workshops and training programs on how to outsource more effectively. Pharma's middle and senior management need to better understand outsourcing. They need to better understand best practices for out-

sourcing. And they need to support their own technical staffs in managing outsourced projects.

MINOR. Every sponsor has a request it sends out that basically asks for the same information, but in different ways. I think if we, as an industry, maybe with PhRMA and the new CRO organization, were to establish some data-exchange standards for information it would be a whole lot easier. This would have to work both ways. CROs could provide their core competencies. Sponsors also would have to identify the core areas they are evaluating.

TAAFFE. Everyone agrees a formal process is required. But it could be simple. In many aspects the CRO industry can be compared with other outsourced activities: legal, finance, and marketing. In these situations detailed bid grids and price per task are not used. Vendors are chosen based on experience and skills, a deliverable is set, a price is agreed on, and the contract awarded.


Bill Taaffe

MINOR. We need an open communication framework, adaptive IT architectures, transparent costing, and shared training. We have to be able to exchange ideas and information with each other openly. We can't hide things from each other. CROs need to become more a part of the internal sponsor team. The communication framework has to be multilayered. There has to be communication between operations, but there also has to be management-to-management communication. If there's an issue at the operational level, where one side is not performing, the management group has to be able to step in and say, 'sponsor, you're not performing, you are holding us back.' We do that to the CRO, but they don't do that back to us.

SUPPLIER analysis

ZISSON. With so much competition among so many CROs from niche to large players, pricing pressures remain a concern. CenterWatch surveys show that 41% of sponsors said they expect to use smaller and niche CRO services more frequently in the coming years. Another 41% of sponsors said they would use a combination of niche and large full-service CROs. Less than one in five sponsors reported they plan to use large full-service CROs more frequently. So the big CROs must overcome the sense that they are too distant and bureaucratic and the smaller CROs must continue to provide personal service while finding a way to seem larger and offer the same technological advantages as the large CROs.

KENDLE. The industry is much more predictable now. Anytime an industry matures, there's a group of leaders that offers a broad base of services or a fairly large base of business. There always will be niche providers. The hallmark of a maturing industry is a broader base of services on a broader volume of business. There's some hope this year that the IPO window will open, at least a bit, and there are companies that hope to enter the public marketplace. This is another sign of a healthy market.

VOGEL. The biggest challenge for the CRO industry is that it has to figure out what it wants to be. I say this because there are basically three strata of CROs — the great big ones, the mid-size ones, and the small ones. The great big CROs are trying to figure out where the profitability is in drug-development services. To that end, many of the big CROs are moving more toward the early clin-

The interactions/relationships between sponsors and CROs have changed considerably over the past few years. In an **EFFORT TO STREAMLINE AND FORMALIZE THE PROCESS** most sponsors now require CROs to conduct all business aspects of a study or program with an outsourcing/procurement department. This new initiative has introduced CROs to a formal RFP process with detailed bid grids and elaborative bid-defense meetings.

ical and preclinical segments of drug development as opposed to Phase II and Phase III studies. There's a perception that there's a greater profit margin there. But, it appears that the fastest-growing component of drug development is Phase IV. Sponsors are increasingly concerned about expanding the area under the sales opportunity curve, which means when their drug is approved and launched into market, they want to launch with the strongest market penetration possible. For that reason, sponsors are increasingly concerned with late Phase IIIb and early Phase IV studies, which are designed to position the drug in the marketplace. That's a very strong segment, and some CROs are looking at that area. There's also recent activity between some of the larger CROs and ad agencies.

ZISSON. Today, CROs have to be more nimble than ever to match the needs of their clients. It's not one size fits all. That's why CROs have expanded their services to marketing and discovery as a way to customize their offerings to sponsors. All of this value hinges on the collaborative effectiveness of the relationship.

CHILDERS. It is a challenge getting the right message to pharma that the CRO industry is very healthy. There are some very strong players in the CRO industry, and as with any industry, there are some weak players. The scientifically strong and financially healthy companies are moving forward and continue to grow, and although a few CROs were unsuccessful and have closed shop, their failures should not overshadow the many successes of other CROs getting drugs to market.

HAYASHI. One of the biggest challenges we face is the current site-selection paradigm. The existing site-selection process is an investigator-centric rather than a performance-centric one. In other words, most sponsors revolve their site selection around the principal investigator's CV rather than an investigative site's performance record. Yet, any site — and for that matter any principal investigator — will say it's the site infrastructure that is the key success factor in executing most clinical trials. Nevertheless, sponsors focus on selecting individual investigators who repeatedly fail to perform rather than selecting the investigative sites that consistently outperform — regardless of any one individual. This is akin to selecting a hotel based on the hotel manager rather than recognizing it is a Marriott-operated hotel.

VOGEL. The reason the CRO industry dramatically began to grow 10 or 15 years ago is that sponsors needed assistance with Phase II and Phase III clinical development. They needed monitoring, data-management, analysis, and to some extent report-writing services. I have some real questions as to whether that's a very profitable business for big CROs to be in. And I think they do too. The smaller CROs have less overhead to deal with. They have less operating costs and they seem to be a little more focused on what I call the core clinical-development activities — conducting Phase II, Phase III studies and providing monitoring, data management, and biostatistics. A few years ago, I stated publicly that I was somewhat concerned as to whether mid-size CROs would prosper, because I didn't know if they could attract enough business to cover their operating costs. In the past few years, they've been doing very well. It seemed for awhile that the larger CROs were grabbing a greater percentage of the business through approaches such as preferred provider relationships, etc., and the mid-size CROs lost some market share. But in the past few years, my perception is that the big CROs are losing some market share to the mid-size CROs. I think the notion of preferred provider relation-


John Cline

> Senior managers are under pressure to report to the stockholders as to how they are improving the efficiencies of the organization. Over the years, the pharmaceutical companies have gleaned all of the efficiencies they can from the paper process. So the next step is **COLLECTING DATA BETTER**.

ships is being redefined. Initially a lot of the deals were cut between CROs and pharma based on volume discounting. Many of these deals failed because sponsors didn't achieve the discounts they anticipated and CROs didn't achieve the volume of business they anticipated. We are still seeing preferred provider or strategic relationships between sponsors and CROs, but they are much more focused on developing master-service agreements, trying to facilitate the front end of the contract, trying to develop longer-term relationships, and developing efficient processes that allow the two companies to work more effectively together across a range of projects.

KAISER. We're focused on building long-term relationships and exceeding our client's needs. We'd rather have fewer clients with multiple projects than have hundreds of clients with one project per client. This requires a continual focus on good communications, quality work, and delivering on time.

TECHNOLOGY analysis

PIAZZA. There is an interest and an acknowledgement of the need for technology solutions to help the drug-development process. There are several areas of electronic solutions for clinical trials, from patient recruitment to discovery tools and techniques to electronic submissions. CROs increasingly are being requested by their clients to offer electronic solutions. If CROs can offer electronic means of doing trials they might be able to achieve higher margins than they can by using old-fashioned paper methods. Whether or not the client specifically requests EDC, the CRO often has the ability to use whatever means it wants to get to the end result more effectively. I don't think there's a company that is not evaluating or looking at EDC solutions. From the CRO perspective, I think things have changed in the last few years. Early on, these systems were seen only as direct competitors to the paper process, the bread and butter of CROs, impinging on their paper process, their data-management process. In the last two years, CROs have come to the conclusion that they need to get on board with electronic solutions — EDC and other e-solutions are not a flash in the pan, they are here to stay. CROs believe that they need to take part in the technology evolution to maintain a competitive advantage and to be on the cutting edge.

> **TECHNOLOGY IS A FORCE TO BE RECKONED WITH.** It elevates the role of our monitors, it enables us to bring efficiencies to sponsors and true economies of reducing the number of visits, reducing the time at site. There are real economies, but as with everything it will take time to adopt. And, technology has to be adopted in a thoughtful and strategic way.

MINOR. We have a tremendous amount of pressure from our upper management to engage new technologies and use them to our advantage. We are looking at EDC, we're looking at ways to push our RFPs and contract development through the Web, and make mutually agreed practices available, so that we can pre-negotiate processes with our vendor pool, and post them so they become working manuals for projects and programs.

PIAZZA. There needs to be process re-engineering. Things will get done differently, but that doesn't mean people lose jobs. There was a fear that CRAs would lose their jobs because all the data would be reviewed remotely, electronically, and there would be no need for CRAs. That's ridiculous, because there is still a need to review the data in person to maintain quality, ensure against fraud, and review source documentation.

ZISSON. Web technology is both an opportunity and a threat to the CRO industry. The role of the study monitor, who provides a lot of revenue for CROs, will change. The paper-based process remains


Christopher Speh


Steve Nelson

Managing sponsor expectations is vital, **CROS DON'T PUSH BACK.** We'll come up with a very optimistic timeline, especially for things like patient recruitment. The CRO should push back and tell us we're being overly optimistic. This would help win the trust of sponsors in terms of estimating project time, cost, and quality.

inefficient and technology will help reduce inefficiencies. As those changes take hold, the role of the CRA will have to expand and focus on activities that support a more effective relationship with investigators, site personnel, and sponsors. Or CROs could potentially lose a great source of revenue from monitoring, which will be reduced as technology is adopted. CROs have already taken an active role in Web technology and will continue to partner, acquire, and compete with those vendors. They may even help consolidate the fragmented electronic data capture industry.

ROSENBERG. The main issue with EDC is that it's sold on the promise of completing studies faster. But other elements must be in place to allow the technology to function well — most notably, the processes that allow quicker response to incoming information. These processes tend to be largely beyond the control of EDC vendors, and the consequence is that these systems generally don't work very well. There are other issues, too, related to workflow in sites.

MINOR. My observation is that not all sponsors are ready to embrace the Web for trials. There are too many platforms with varied results. There's little guidance from the FDA or from PhRMA about what standards we should start to look at. This makes it very difficult to get consistent results using the Web for trials.

CLINE. Philosophically, the use of technology also requires simultaneous process change. Technology can create as many problems as it solves. Therefore, technology plus process change equals success. Electronic data capture has been around, in some form or another, for 10 or 12 years. Less than 10% of trials are done electronically, but that's changing rapidly. There are a lot of efficiencies that CROs can glean and pass on to their customers by using EDC. As more and more drugs become available through genomics and proteomics, even the CROs will have trouble sourcing the right people to do the outsourcing work for their clients. A CRO or pharmaceutical company using EDC will be able to produce more work for whomever the client is, either internal or external.

PIAZZA. All of the different electronic solutions that are being highlighted right now — EDC, clinical-trial management systems, submission systems, adverse-event collection systems — had been separate, unique products and applications. These are now becoming integrated systems that talk to each other and work as a single system. Sponsors won't have to go to different places to get little pieces of data here and there. The integration of electronic systems is getting more popular and is in more demand, and that's going to continue to grow.

ROSENBERG. The way EDC works at the site is that the data have to be collected on a piece of paper and then be entered into the system. That turns the site personnel into data entry clerks, for at least part of their time. These are expensive clinical support people, who do not like to do data entry and are not particularly good at it. We were among the first in the industry to do EDC trials back in 1993, but we have backed off EDC because it generally does not work well from a site perspective. We're doing almost all of our studies with machine-readable paper CRFs that utilize optical mark-read technology, not optical character read. We find that this system, coupled with the other elements we have, works far better than the systems in the field that use EDC as the sole component, and we have extensive performance metrics that reflect this fact. The real bottom line has to be how fast does the technology enable a study and a development program to be completed. The system must focus on user issues and a host of other elements to arrive at a solution that benefits the bottom line — getting submissions in faster.

CLINE. Technology wasn't very friendly up until four or five years ago. As the adoption of technology becomes more prevalent, I think doctors, who have used computers as part of their everyday life, are not only are going to drive the EDC business, but the total electronification of their practices.

VOGEL. I am amazed that we haven't made EDC ubiquitous at this point. EDC has been around for more than 20 years. The problem is not a technical issue,


Eric Hayashi

It's common knowledge that 80% of projects fail to meet their originally targeted enrollment deadlines and clearly the cost of this lost time is enormous. **TWO CULPRITS** — both solvable — are a **BROKEN SITE-SELECTION PROCESS AND MISGUIDED INVESTMENTS**, or lack thereof, in participant recruitment activities.

it's a relational issue. Its adoption has to do with the fact that healthcare professionals are paper-and-pencil oriented rather than computer-oriented. This is changing as new generations of healthcare professionals are coming in. I think EDC also is complicated by IT people in pharma who tend to want to have their own processes rather than buy off-the-shelf solutions. Again, this goes to efficiency. I think if a CRO or a network of sites were all using the same EDC system, and simply set up a way to translate or integrate their system with the sponsor system, there would be tremendous efficiency.

CLINE. Senior executives at pharmaceutical companies are mandating to their therapeutic area heads that they must do "X-percent" of trials electronically. Senior managers are under pressure to report to the stockholders as to how they are improving the efficiencies of the organization. I firmly believe that, over the years, the pharmaceutical companies have gleaned all of the efficiencies they can from the paper process. So the next step is collecting data better.

VOGEL. I think the pharmaceutical industry and CROs have been very slow to integrate technology into drug development. There's a lot of good stuff out there. For example, using computer modeling to design more efficient clinical trials. Twenty years ago, people were writing clinical protocols without any idea of the statistical probability that the protocol could actually detect an active drug. People used to write protocols without statisticians being involved and without knowing the power of the protocol. Now, it's commonplace. The question becomes can we get to the next step and use computer models to actually run the trial in a virtual sense to evaluate different scenarios? If so, we could better design the protocol, evaluate entrance or exclusion criteria, and project enrollment based on different criteria. Sponsors tend to develop protocols by what I call successive approximation. They write the ideal protocol, start the study, find that they are having problems finding pristine patients, then they amend the protocol. It takes a lot of time and effort at the regulatory agency to review all of the amendments. This causes a lot of disruption in having to redefine the project with the CRO. Computer modeling might be able to help in this regard.

CLINE. Technology can significantly reduce monitoring costs if companies redo their processes. Right now, monitors have to get on a plane and go to Oklahoma City to look at paper case report forms. But if I am that same monitor, I can sit at the home office, go online, and do four or five different sites in a day. The monitor would then only have to physically go to the sites when source documentation verification was needed. Monitoring is a very, very big piece of the total trial process. The winners of tomorrow are going to be those CROs and pharmaceutical companies that adopt technology, and more importantly, adopt process change. These companies will be light years ahead.

TAAFFE. CROs can make a real impact on the timelines of drug development. They have fine-tuned the process with state-of-the-art technologies and are not delayed by competing internal priorities. It is the only thing they do. The real gain for companies in using a CRO is the value of time saved because the study is completed more quickly.

HAYASHI. E-technologies frankly have created more work at our sites than sponsors realize. Most RDE technologies, for example, simply shift the data-entry tasks to the site rather than what previ-

ously was performed by a data-management group. We have to enter all the data now, before they did that. We have to deal with the data-entry system glitches, before they had to deal with that. We still develop source documents and transcribe those source documents into the remote data-entry systems. However, from a competitive standpoint, this works to our advantage because all of our sites, as a SMO, are supported by a sophisticated IT infrastructure and have the ability to work with any RDE/EDC platform.

SPEH. We have to be careful of false economies in relation to technology. There's no doubt in an electronic environment that all of the data, after the internal checks, will be clean for the most part. If a sponsor is using an electronic platform and using it appropriately, a site can be closed and the data locked within a couple of weeks. The false economy comes in because there's a major investment up front to ensure that the sites are outfitted with the equipment, training, and capability to work effectively in an electronic environment. Much of the work, which was formally the responsibility of the sponsor or data group, is now being pushed to the site. And the sites aren't necessarily compensated. The sites bear a real cost, whether it's covered in the budget or not. Typically, a sponsor will capitalize the site if the site doesn't have the technology but that's the least expensive of the options. From the sponsor's view, they are compressing two job functions into one. In the old days, the site coordinator was expected to manually collect data on case-report forms or data-collection forms, which went to the data-collection group, either at the sponsor, a data firm, or CRO where those reports were key punched. Two functions were being undertaken to deliver one set of data. What the sponsor sees, and what the data groups are saying, is that those two functions are now compressed into one. In the view of the sponsors, the sites aren't being asked to do any more than they were doing before. In the site's view, there are still two functions — the data collection and the data input. There is a disconnect between what the site perceives and what the sponsor is perceiving based on what the e-platform groups are telling them. Clearly if these technologies are applied appropriately at the site and within the sponsor setting there can be real efficiencies. But I'm not certain that we've yet translated those into economies. These days time is much more valuable to a sponsor than cost, so there are very real potential benefits to sponsors using technology in this way.

KENDLE. Web technology is not helping much, although we all wish it would. Our customers are still fairly uncomfortable with data collection and data security outside the medical affairs and medical marketing arena. Collecting data over the Web on a marketed product is entirely different than trying to collect data on yet-to-be approved products. We were so hopeful that patient recruitment would be done via the Web. Yes, we can get some touchy-feely data on actual patients who might be out there, but the really hard work of finding the appropriate patient hasn't been greatly improved by the Web. We're just not there yet. We can collect a lot of names, but whether or not they qualify is the real issue.

SPEH. Technology is a force to be reckoned with. It elevates the role of our monitors, it enables us to bring efficiencies to sponsors and true economies of reducing the number of visits, reducing the time at site. There are real economies, but as with everything it will take time to adopt. And, technology has to be adopted in a thoughtful and strategic way. We've seen some sponsors mandate the adoption of an e-technology platform, and the clinical teams have to figure out a way to make it work. That's not a strategic decision, that's a tactical decision that may or may not have applications for the study being pursued, and could be a costly mistake.

Ad Agencies Look to CROs for Expanded Sponsor Relationship

Torre Lazur McCann Healthcare WorldWide, a global healthcare marketing communications, medical education, clinical publishing and consulting group, has acquired Target Research Associates Inc., a contract research organization.

Torre Lazur is the latest agency entrant into the CRO arena. Torre Lazur follows Omnicom Group Inc., which in 1999 purchased a significant minority stake in Scirex Corp.; Interpublic Group of Companies Inc., also in 1999 purchased International Pharmaceutical Research, to be part of its Lowe McAdams Healthcare unit; WPP's CommonHealth formed a joint venture through its HLS Clinical Systems division with Advanced Biologics LLC; and Gerbig/Snell Weisheimer & Associates Inc. formed a strategic alliance with PharmedicaResearch Inc. (GSW no longer has a formal alliance with PharmedicaResearch, now called Registrant Inc., but still works with the company on select projects.) This vertical integration model is one way for an ad agency and a CRO to focus on the full commercialization needs that sponsors have.

Target, which is based in New Providence, N.J., with additional offices in Philadelphia and Chicago, provides the traditional CRO services of clinical-study development and management, monitoring, data management, biostatistical analyses, and medical writing.

The company, which was founded in 1992 by Lloyd Baroody and Izabela Roman, M.D., Ph.D., will continue to operate under its own name and management.

According to Joe Torre, chairman and CEO of Torre Lazur McCann Healthcare, a McCann-Erickson WorldGroup company, the acquisition of Target is Torre Lazur McCann's own first entry into the clinical-research field.

Lloyd Baroody, CEO of Target, says, "Because Torre Lazur McCann and Target have the same type of pharmaceutical, biotech, and medical-device company customers, Joe and I see many collaborative opportunities in our joining this leading global healthcare group. There are significant untapped synergies that can result from combining CRO services with the wide array of complementary services offered by the Torre Lazur McCann constellation of companies."

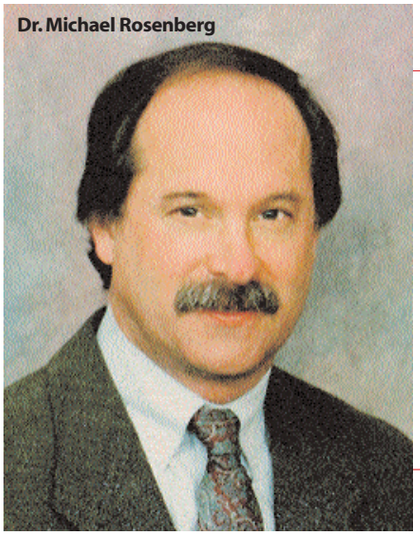
Target is involved with a client while a drug still is in development. TLM's worldwide group of complementary specialized services also includes such companies as Complete Medical Group (U.K.) and Scientific Frontiers (U.S.) in scientific and medical publishing, Caudex (U.K.) and MPE, CMS and HealthVizion (all U.S.) in medical education, Magister (U.K.) and Global Research and Migliara Kaplan (both U.S.) in consulting and market research. TLM's group also includes communications and ad agencies comprising two global networks.

KENDLE. If there's any competitive advantage around technology, it's around technology used to manage a project worldwide. After that, advantages are in worldwide learning — e-learning — or in the medical affairs and medical marketing collection of data over the Internet.

CLINE. Ultimately, technology is only going to get better. What is really exciting is getting drugs to market quicker. I think sometimes the industry loses sight of that. We actually do social good on top of being a for-profit business. People get hung up on technology, but just as important is service to the client. A lot of technologies will get a CRO or pharma company to its ultimate goal, but the question is how quickly does the technology get them there? And, at what pain level?

PERCEPTION analysis

CHILDERS. There's a misconception in thinking of contracting as a way to lower costs simply by hiring cheaper staff. Cheaper shouldn't be the focus. A product worth investing in should be worked on by a professional and skilled staff. A CRO's cost structure is no different, it can simply be utilized more efficiently as it is a job we do day in and day out. It's all about seizing the opportunity to get more products developed. With outsourcing there's a tendency to think about finding an equal partner who has something to contribute.


Dr. Michael Rosenberg

The CRO needs to be able to **BRING SOME CAPABILITY TO THE PROJECT THAT THE SPONSOR DOESN'T HAVE.** There are two elements to that. One is the technology component. Secondly, currently the most common model, especially among big pharma, is to use outsourcing as a rent-a-body approach. But increasingly, what companies are looking for is an organization that can improve the overall goal of improving the efficiency of the development process.

KAISER. When someone says contract research it doesn't have a positive spin. We like to say drug-development service provider, because we're trying not to be a fee-service based entity. We're trying to provide more than a one-time deal.

MILLER. It takes time to build good interpersonal relationships between a client and a vendor. There has to be the expectation that both sides are going to make mistakes since we are all human. What's important is how these mistakes are handled, and how we move forward to avoid repeating them. This is predicated on the fact that we are working towards the same common goal.

VON RICKENBACH. We view ourselves as a biopharmaceutical outsourcing company, rather than a contracting company. Contracting implies more of a temporary performance of certain tasks rather than a partnership with a longer-view perspective.

LAGROTTERIA. I view outsourcing as partnering versus contracting, which is like purchasing. In outsourcing, we're looking for ways to help each other get what we want more efficiently and effectively. Contracting or purchasing is more tactical — every single time we have to recreate the wheel. Products or services are viewed more like commodities. Outsourcing is more strategic in nature and allows everyone to take a longer-term view. With outsourcing everybody is on the same side of the table looking at the problems or issues together, anticipating and coming up with contingency plans and looking for ways to get the job done a lot more smoothly. A contracting arrangement puts us on opposite sides of the table.

TAAFFE. There have been many conferences debating different approaches to better CRO/sponsor "partnerships." The consensus opinion is that it would be advantageous if there was a relationship where the CRO was involved with the sponsor in their annual portfolio planning. In this way resource planning and allocation would be optimized, matching the program with the appropriate skills. This would be true outsourcing where there would be leverage of core competencies. What we have now is probably closer to contracting and out-tasking than it is to real outsourcing.

SPEH. The relationship between pharma and CROs is changing. There are sponsors that are more progressive than others. Sponsors that view these relationships not as a one-way relationship, but as a way to share information in a meaningful way with their vendors, are finding that their projects are more successful than the sponsors that continue to outsource studies in the same way they contract for painting or grass cutting. Clinical research is different, it's more complex, and the more pharmaceutical sponsors embrace a fuller relationship with their vendors, the more they benefit.

KENDLE. Outsourcing has a broader feel. Whereas contracting implies fixed service or a smaller amount of business or a shorter time interval. Kendle was one of the first companies in our industry; we predate the CRO label. We wanted to be referred to as a consultant; we didn't want to be called a contract research organization. Then, we all got comfortable with the contracting word, which implies buying a group of services. And now, we're more comfortable with the outsourcing word, because again it signifies the depth of the relationships we have with our customers.

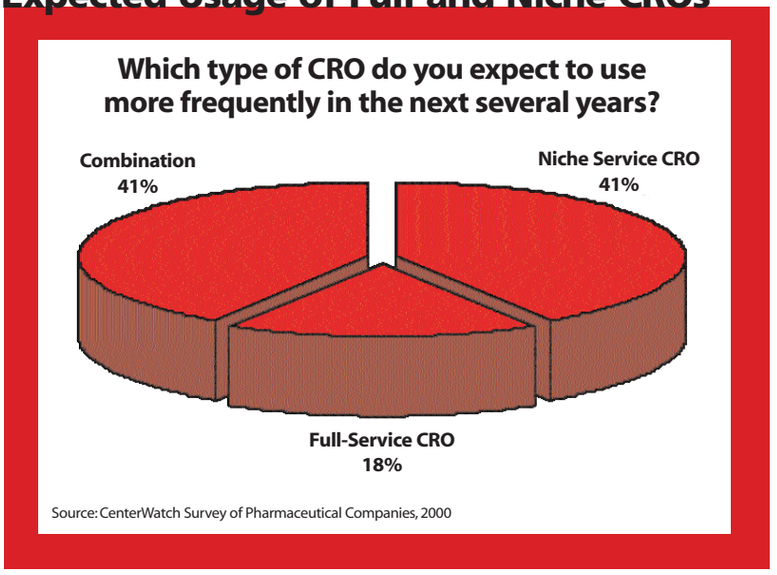
RISK analysis

SPEH. There's a lot of talk about risk sharing. When it's broken down, I'm not sure it's really delving into either risk or sharing. What we have found is there are some sponsors who have tried to elaborate that term in their contracts. One sponsor wanted to outsource all of the risk of the program along with all of the studies in that program. On the face, that sounds like a pretty good deal. The CRO has the opportunity to make some money by bringing in the program successfully. But by outsourcing all that risk, the CRO has to have a crystal ball that is better than the sponsor's in anticipating and responding to unintended world events. To think that a CRO's crystal ball is any better than a sponsor's is faulty. Additionally, the sponsor effectively has become totally dependent on the CRO to deliver the product. That may sound attractive, considering the pressure on pharmaceutical companies to meet Wall Street, shareholder, and senior-management expectations, but in fact this introduces a whole new level of risk in the sponsor environment. Because the sponsor has outsourced the program risk, it has now in-sourced a strategic risk that a program may not be delivered successfully. If the company were doing the program itself or working in a more traditional, collaborative way with the

CRO, it would be able to step in and take mid-study corrective action to get a program back on track. In my view, a CRO that bids aggressively on a program like that, and is willing to face that kind of risk, is a bit desperate for the business.

PIAZZA. For everyone to be successful, partnerships between vendors and CROs need to be structured so that everybody gets what they need. Everybody needs to be profitable, and everybody needs to have systems that they can use routinely and effectively. This may be easier said than done because there's still the thought by CROs that if they use systems, they might lose their margins, their people, their control. And the vendor is thinking, if we partner with CROs do we lose whatever advantage we had within the sponsor organizations? Do we become more of a third party to the sponsor?

Expected Usage of Full and Niche CROs



MINOR. Sharing in risks means that everybody has something on the line. It's not just one sided. I don't know that anybody is doing that well or doing it consistently. The contract should not be the technical manual for a project, that should reside in the domain of the operational group. We have started to look at ways to collect and document the processes, and negotiate the processes with the CROs. When Pfizer has a request for proposal to put out, basically we know, on both sides, what resources are going to be engaged, how long it will take to create a deliverable to our standard, and what the makeup and the documentation of the deliverable will be. From that perspective, we can pre-negotiate prices without going to a preferred vendor pool. We established a set of working guidelines that any company working with Pfizer can follow. Then we simply look for the best team to execute. It takes price out of the equation.

CHILDERS. I like to work off opportunity. We can't be fearful, we have to look from an opportunistic standpoint of how to do things better and faster for our clients. Fear can force us to make bad decisions, in which the benefits of a collaboration are pushed further away. There is a choice, an opportunity to do good or instead to try to ensure that any potential downside is covered in a contract. Contract initiation has drastically increased over the years, everyone is looking to create the infallible super-contract that in the end can delay a project start and potentially increase the time it takes to get a product to market. Magellan wouldn't be a company today had we listened to the overriding fears instead of the opportunities.

ROSENBERG. Risk sharing is a great concept but one that is difficult to execute. The reason why it's difficult to execute, is that in drug development there are always twists and bumps and we never know when they are going to come, but we know they'll come some time.

KAISER. For smaller companies, the benefit of the shared risk/shared reward is that if they don't have the money or the backing to move forward, this is where we can help them. We can provide the services that they need to get them where they are going. This is a way that a biotechnology company or small virtual company can move forward.

LAGROTTERIA. Over the past few years, with the development of more formalized outsourcing divisions within many pharmaceutical companies, the concept of "risk sharing" on clinical-trial programs has arisen. Usually, this concept relates to meeting mutually defined development milestones, with the CRO "sharing" the risk by taking a financial incentive upon meeting the milestone or a financial "risk" for failing to meet the milestone. Such milestones are commonly first patient in, last patient out, a locked database, final report, etc. We have successfully engaged in this risk-sharing model with several pharmaceutical companies. The keys to success for "risk sharing" are found in the word "sharing." Both the contract research organization and the pharmaceutical client are agreeing to take responsibility for key deliverable items on the timeline. This shared responsibility places the program into a context that is mutually acceptable, and ultimately drives toward program success. Underlying the success of any program is almost military-like precision in project management, with obstacles identified and resolved before they impede the critical path. We think that we have proven that we have the human management and technical and clinical skills to make "risk sharing" a "win-win" for our clients.

VON RICKENBACH. The term "risk-sharing deals" is a bit of a misnomer in the sense that whenever a company shares risk, it also expects to share the rewards. These arrangements really should be called "risk-and-reward." From my perspective, some of these arrangements have proven successful, while others have not. Moving forward, particularly with the advent of new drug technologies, there may be attractive opportunities for companies like Parexel to enter into these types of risk-and-reward sharing arrangements with clients.

KENDLE. Risk sharing outside of equity is not an area where we've found business partnerships. We do not have equity sharing partnerships. We know some of our competitors do, but that's an entirely different issue. And, it's very product specific and situation specific. I think we would take the approach many of our competitors have taken; that is, if it were the right opportunity, we would do it. That's entirely different than risk sharing around developing another company's product without the benefit of equity. ✦

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