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JACQUELINE CURTISS
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EMD Serono

DR. AZMI NABULSI
Deputy CMSO and Head, Strategic & Professional Affairs, Takeda

How to Overcome The Challenges Of A Single-Provider Model

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CRO LEADERSHIP AWARDS 2017

Meet the 2017 CRO Leadership Awards Winners

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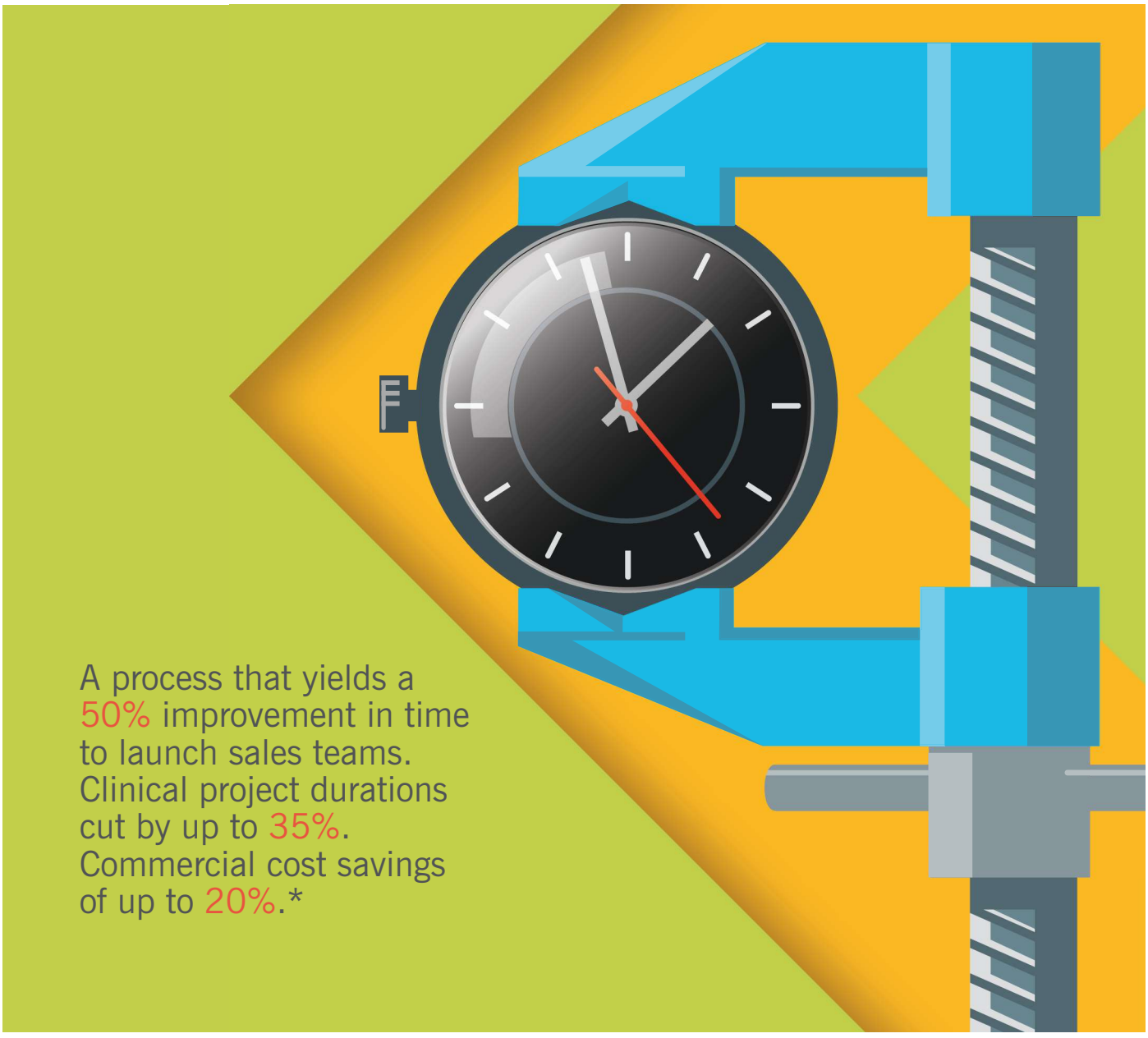

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CRO Partnering:
The Only Constant Is Change

ED MISETA Chief Editor, ClinicalLeader.com

"Change is the only constant in life." That quote is attributed to Greek philosopher Heraclitus, but its theme still resonates today in many areas, including pharma. When it comes to clinical outsourcing, it certainly seems like the only thing that doesn't change is change.

Last year when I prepared this annual CRO Supplement, our cover story featured Corsee Sanders of Roche. While most of the article centered on combining analytics with clinical operations, Sanders did note another major change underway at the company: Roche would focus on managing late-stage studies within the company, with few exceptions. Only site monitoring would be outsourced.

Certainly some promises related to strategic outsourcing have thus far failed to come to fruition. One article in this issue from The Avoca Group focuses on sponsor survey results and notes several areas of dissatisfaction. But if you thought the era of outsourcing to strategic partners might be coming to an end, think again. In this issue you will read about the efforts of two companies, Takeda and EMD Serono, that each opted to form a strategic agreement with one CRO. All clinical trials will now be conducted by that single CRO partner.

Some in the industry think strategic partnering is still a dream of only large pharma companies. But as you'll learn in this issue, 62 percent of sponsors now consider themselves to be in a strategic partnership, an increase of 27 percent over 2011. Yet many small to midsized companies will still tell you they are not large enough to even consider having that type of relationship with one CRO. They continue to try to make some form of the functional service provider model work for them. In fact, despite the rise in strategic partnerships, 79 percent of sponsors still tout working with four or more CRO partners.

No model of outsourcing is perfect, and every variation of it will come with strengths and weaknesses that sponsors will be forced to navigate. The pros, including more timely, efficient, and cost-effective trials, are enticing. But the cons, including lack of cost savings, staff changes, and providing proper oversight, will continue to keep operations personnel awake at night. Among sponsors, there has been a double-digit decline in satisfaction with access to high-quality personnel. Furthermore, the number of sponsors noting their goals for cost savings are being met dropped from 48 percent in 2011 to 45 percent in 2016.

Is there a solution? One new alliance comprised of service providers thinks there is. The consortium, composed of five service providers including inSeption Group, FMD K&L, and Pyxa Solutions, believes the solution starts with leveraging the strengths of each member organization across all functional areas of R&D. The promise is knowledgeable personnel, a seamless integration with one point of contact, and greater transparency over trials. Will this new model work? That remains to be seen.

One thing is clear — challenges to outsourcing remain, and sponsors will continue to work at becoming fully operationalized with their partners. Change will remain an integral component of every outsourcing relationship, and we hope to see the day when all of the promises of strategic partnering come to fruition. In the meantime, Heraclitus would be proud to know his words continue to bear on the clinical world.

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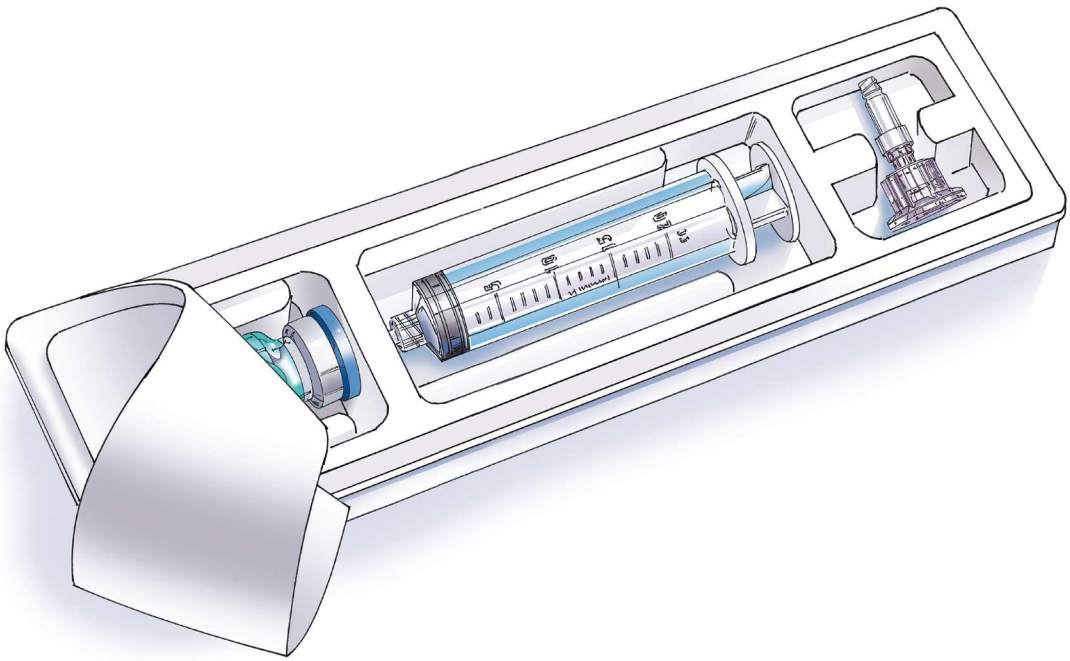

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For years, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany used a mixed clinical outsourcing model. The company conducted some trials in-house but outsourced others to external service providers. For trials in development around the world, the company had four global CRO providers. For regional Phase 4 and label expansion studies there were as many as 100 different providers, which included niche CROs from around the world.

Merck KGaA, Darmstadt, Germany acquired Serono in 2006. Soon thereafter, the company closed the Serono hub in Geneva, Switzerland, and also decided to outsource the entire trial portfolio to CRO service providers.

A New Strategy And A New Model

The changes made at Merck KGaA, Darmstadt, Germany were primarily the result of an initiative called "Fit For 2018," a transformation and growth program ahead of the company's 350th anniversary in 2018.

"The operations group was asked to come up with a model that would allow us to conduct clinical operations in a manner that was faster, less expensive, high quality, and more efficient than our previous model," says Jacqueline Curtiss, the company's global head of clinical trial management, global clinical operations. "We knew it would be a fully outsourced model, but other than that we were given no parameters or restrictions. As a team, we just needed to figure out how to get it done."

Questions were raised whether this type of outsourcing model would actually save the company money or if the company would maintain adequate accountability over the trials — and whether a CRO could run them better than the sponsor. What would be the efficiency and effectiveness of a fully outsourced model?

The decision ultimately came down to cost and expertise. If the company was in a position where it had to undergo change, then why not find those areas of expertise that could be most easily outsourced? This operational piece was really just one component that would change how the R&D organization operated.

Bring The Right Minds Together

Once the decision was made to outsource all trials, a decision still had to be made regarding the number of outsourcing partners and who those CROs might be. As any operations person will tell you, selecting the right partner is never an easy task.

"The cross-functional team went through a very detailed process that involved dedicating almost a full week's time to discussing the advantages and disadvantages of a sole provider, and whether that would work for us considering the size of the company and our portfolio, as well as the global reach of the trials we had in development," said Curtiss.

Some felt outsourcing to one CRO had its advantages, while others were concerned about transferring all trials to one partner. One of the biggest questions that came up during the process was whether the company had a large enough portfolio to justify two CRO partners. Another concern was whether that portfolio would be important enough to two large CROs if it were to be split in half. What resulted was a complex and pointed conversation.

There was a cross-functional group of about 22 people in the room. Clinical operations were a big part of it, but the group also included medics, statisticians, data managers, and representation from the early development team. Every department that could potentially be impacted by the decision had a voice present.

The Risk & Rewards

Of A Fully Outsourced Clinical Model

ED MISETA Chief Editor @EdClinical

Jacqueline Curtiss, Global Head Of Clinical Trial Management, Global Clinical Operations, EMD Serono

Inside A Massive Outsourcing Shift

When the biopharma business of Merck KGaA, Darmstadt, Germany made the decision a few years ago to outsource all of its clinical trials to QuintilesIMS, it created a challenge Jacqueline Curtiss and her colleagues would have to solve. Curtiss is the global head of clinical trial management at the Biopharma business of Merck KGaA, Darmstadt, Germany and was part of the team tasked with overseeing the process of moving all trials, including those being conducted internally and at other CROs, to its new partner.

Moving just a single trial from one CRO to another can be a challenge, but Curtiss notes moving all of your ongoing trials to that one provider required a tremendous undertaking. A clinical trial cannot be moved overnight, and transitioning those trials to the new service provider took approximately two years to complete.

"The first thing we did was perform a gap analysis to determine if it would be feasible to transition all trials in progress," says Curtiss. "We had studies that were close to completion, either in-house or at another CRO. If it made sense to finish rather than transfer them, that's what we did. The main priority was maintaining proper treatment for patients involved in the studies and ensuring there were no disruptions. All other concerns, including cost and time, were secondary. When a patient showed up at their site for a visit with their physician, we wanted that to be a seamless experience for them."

The first trials transferred were the ones most recently launched or in the process of being launched. Transition teams at both companies were created to ensure the transfers were conducted smoothly and properly. The process was complex and often required the company to pay the new CRO for work that was already completed by another provider.

"This was a massive effort," states Curtiss. "Contracts that were already in place needed to be changed. Documents had to be refiled with regulatory authorities in all of the countries where we operate, and sites needed to be notified. Some of those documents were very complex, which contributed to the challenge of the transition."

Maintain The Right Skill Sets

Throughout the process, retaining top talent was a priority — qualified people to continue the work during this transition. At the same time, QuintilesIMS needed to make sure it had staff available and prepared to take on the additional work. Finally, the individuals maintained internally also had to have the right skill sets. For example, someone who was leading a trial in-house might not have the skills and experience to manage a study that was outsourced. Curtiss notes this was a critical part of the conversion effort, as the two jobs require entirely different skill sets.

"Managing a CRO is not as simple as saying, 'I know what work needs to be done, so I am capable of telling someone else what they need to do,'" adds Curtiss. "Teaching people how to lead and ensure proper vendor oversight versus performing the work yourself is a hugely underestimated training need. These are two very different jobs. Once we opt to outsource a trial that had been done in-house, we need to release control (but not accountability) of the study to the CRO and let them do what they do best. Our job at that point is to provide oversight and set the strategic direction. We have to be able to demonstrate to regulators that we are maintaining control over the trial and ensuring patient safety, while also releasing some of the day-to-day activities and tasks to the CRO. That can be a very delicate balance."

As noted earlier, a primary goal was maintaining treatments to patients. There were approximately 15 trials that had to be transitioned to the new CRO. While a lot was changing in the background, including contracts and the CRO representative at the investigative sites, there were no gaps in treatment for the patients, and most would not have known a change in CRO even took place.

Do What You Do Best

Although the biopharma business of Merck KGaA, Darmstadt, Germany has a large and competent legal team in house, it opted to have its new CRO partner do most of the contract work with sites due to the huge increase of workload during the transition. The pharma company provided QuintilesIMS with language it found acceptable and asked that new contracts be negotiated using that language.

Allowing the chosen CRO to do things its own way was a new way of working. The two companies had to develop a plan for how to work together, which Curtiss notes was another important focus area.

"We realized quickly that change management was key to the success. Leveraging the skills and expertise of both companies and bringing them together to create one team allowed us to really optimize the strategic intent of the partnership. Change isn't easy, but everyone has made a concerted effort to make this collaboration a success for patients."

Change management was an important consideration for bringing that large a group together. Management knew that moving forward with a complete outsourcing model would require buy in from key stakeholders at every level of the company. It was clear that this task would be challenging, but with the size of the company and its portfolio, it was a move that made the most sense for the company.

One Development Engine And One CRO

During the decision-making process, Curtiss notes she never believed the company would opt to align itself with just one CRO. However, she knew many pharma companies and their CROs often seem to have overlapping activities. That was something the biopharma business of Merck KGaA, Darmstadt, Germany wanted to avoid.

> We knew it would be a fully outsourced model, but other than that we were given no parameters or restrictions. As a team, we just needed to figure out how to get it done.

"Trust is an important element between pharma and CROs," says Curtiss. "Oftentimes the CRO waits to be told what to do to ensure they get paid for doing it. But when that happens, they do not have any responsibility for what is being done because someone from the sponsor company told them what to do. That dynamic doesn't work well."

That is when the team came up with the idea of employing a model where there was a single development engine for the company. The model would ensure there was no duplication of effort and would feature an external development team that functioned as an internal part of the company. There were questions around whether it could actually be done and even if there were a partner that would be willing to participate. Still, Curtiss and many of the team members felt this was something that could work. They also realized there was no way it could work with more than one CRO. No one would see the logic in having a "single" external development engine that consisted of more than one partner.

Show Us What You Can Do

To help with the selection process, the biopharma business of Merck KGaA, Darmstadt, Germany created a bid grid, which helped it

define what the company needed. The grid was like a decision tree that created a list of potential service providers that was then winnowed down. Initially there were eight CROs on the list. Because the biopharma business would be fully outsourced from end-to-end, the process of getting down to four CROs was relatively easy. Several of the CROs did not have the desired capabilities and would not be able to help the company with its early planning work. From there it got a bit more difficult. A significant amount of time was spent evaluating the final four CROs.

"Each of the four CROs was sent a profile of one of our molecules," says Curtiss. "We simply said, 'Develop this for us.' No other directions were given. We wanted them to come up with a development plan, whether it was right or wrong. We just wanted to know that they had the expertise and the staff to be able to do this, as well as the commitment to actually sit down and get it done. It also allowed us to see what each CRO considered to be a good clinical development plan in this highly competitive landscape."

The four CROs were then brought in for a structured, day-long meeting with the cross-functional team. The meetings were run exactly the same for each CRO, and the entire team received a thorough download at the end of the day on the performance of each CRO.

"The mornings were set aside for us to evaluate their development plan," says Curtiss. "The afternoon featured breakout sessions to determine standard capabilities, such as IT, medical, and regulatory. I was in the session looking at the clinical trial management system (CTMS) to determine how our systems might work together and interface."

Once the meetings were over, the team unanimously chose to pursue a one-CRO model, with QuintilesIMS being the unanimous choice and the primary partner for trials in Phase 1 to 3 and even some Phase 4 work. (Depending on the scope of the trial, another CRO could be used in some specialty cases, and a very detailed process notes how and when the company can go outside the partnership.)

Some Got It, Others Didn't

The evaluation team knew the CRO selected would have to offer end-to-end services. On the back end, they would have to understand the needs of regulatory submissions. But that is the easy part. On the front end, the partner would have to help the company determine the clinical development plan based on their operational feasibility, understand the indication, know what countries to work in, and how to best develop the asset. That was the more challenging part.

"We felt there were few CROs with the capability to bring that end-to-end offering to the table," notes Curtiss. "Our meetings really forced us to test them on that early development piece. We needed to know if they could provide the operational expertise necessary to develop the molecule. But we also needed to know if they had the global reach to pull it off. There are not many CROs that can run a large global Phase 3 trial in the number of countries where we operate. Third-party vendors play a role in the clinical process. The CRO would be allowed to pick those vendors but would also have to be competent enough to manage them throughout the course of the trial."

> Oftentimes the CRO waits to be told what to do to ensure they get paid for doing it. ... That dynamic doesn't work well.

When it came to demonstrating its capabilities to develop a molecule, some CROs seemed to understand the assignment while others did not. Curtiss notes some CROs brought the wrong people to the meeting. Others brought a team that attempted to make a sales presentation. This did not allow the cross-functional team to see what they had to offer or if they would be able to embrace a different way of thinking that involved doing a lot of the planning rather than simply following direction.

"We started this process in 2012 and made our final decision in 2013," says Curtiss. "It takes a significant amount of time and energy for a true partnership to begin to deliver benefits. Your portfolio, teams, and the industry will all undergo changes. In addition, you need to be willing to adjust your model as the situation changes. This includes a continued need for sponsor oversight and associated applicable regulatory requirements. It's important to give these partnerships time to mature."

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TAKEDA OUTSOURCING MODEL SEEKS THE BEST OF BOTH WORLDS

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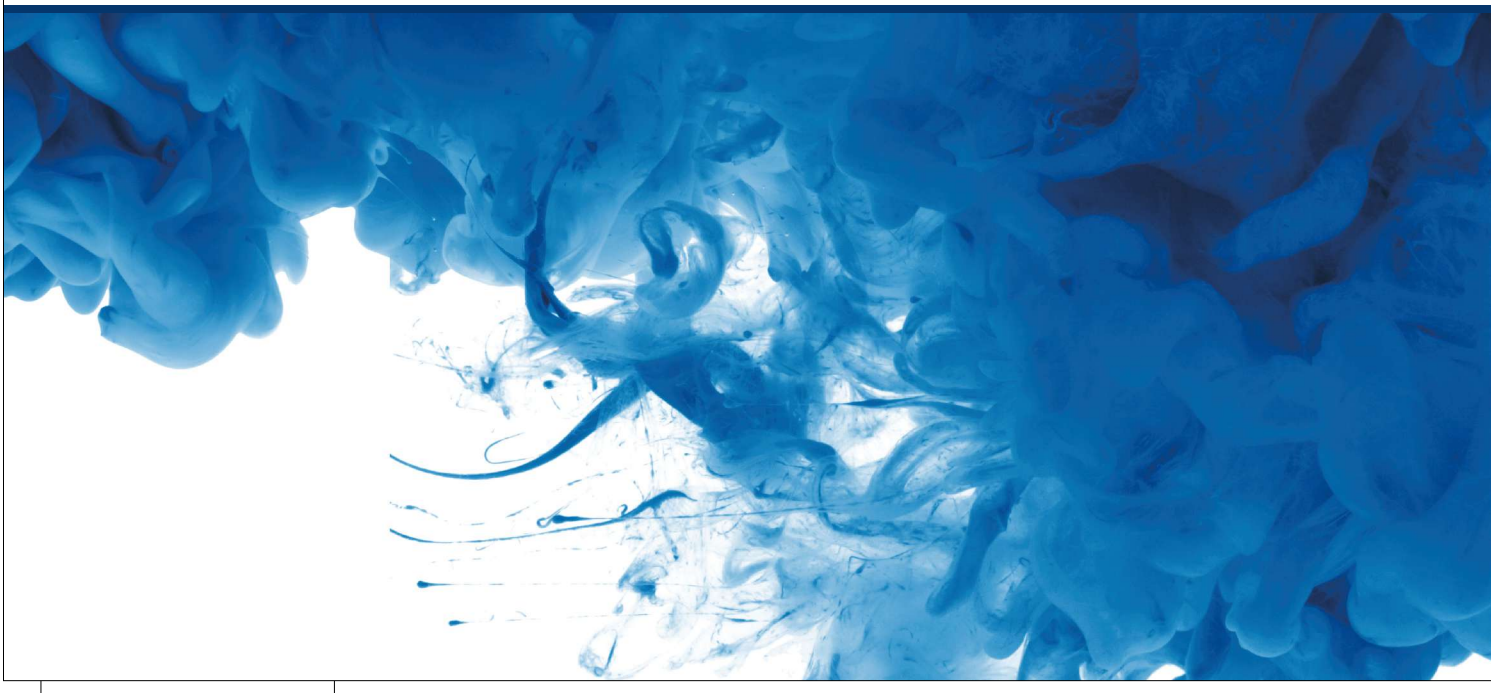


DR. Azmi Nabulsi will tell you that one of Takeda's principal beliefs is that it cannot do everything on its own. Therefore, the company strives to achieve excellence in R&D by working with trusted partners. As the deputy CMSO (chief medical and scientific officer) and head of strategic and professional affairs for Takeda, Nabulsi understands that the benefits of those partnerships can manifest themselves in everything the company does, from bringing new compounds into the pipeline to increasing operational efficiencies. The strategic partnership Takeda formed with PRA Health Sciences last year was a major part of that philosophy and the company's drive toward excellence in clinical trials.

"We looked at our clinical trials and asked ourselves how we could better execute those studies," says Nabulsi. "We were not only interested in the area of clinical operations but also in optimizing pharmacovigilance and the regulatory operational elements. Like many other companies, we have moved from being internally driven to doing more outsourcing with CROs."

But that wasn't enough. To achieve true operational excellence, the company wanted a model that would give it the best of both worlds. In other words, the sourcing flexibility and efficiency of an outsourced model matched with consistency in talent and experience of an insourced model. "We needed a model that embodied all of those elements, with the hallmark being excellence," adds Nabulsi. "We started designing that model, and in the end, we came away with an exclusive partnering agreement with one company running our trials and other operational activities."

A DIFFERENT KIND OF RELATIONSHIP

For Takeda, deciding it wanted an exclusive outsourcing partnership was the easy part. Once that decision was made, selecting the right CRO was a process that involved a lot of personnel and a great deal of time and thought. Nabulsi notes that the company spoke to a number of potential CROs and explained its vision. The internal R&D leadership team handled the interactions, and the therapeutic, functional, and operational area leaders were also heavily involved in the process.

Takeda started with a list of five CROs it had worked with in the past. Although the company had worked with almost all of the prominent CROs, these five were the ones that seemed the most open to having serious discussions about what the company hoped to accomplish. That list was quickly whittled down to the top three that seemed to be most comfortable with the discussion. The dialogue with potential partners involved how they would approach the relationship and how they would take Takeda's vision of an outsourcing relationship and make it operational.

"We did not want a traditional CRO relationship, and we needed our potential partners to understand that," says Nabulsi. "We were not embarking on this relationship simply to drive cost or speed. This was not about the traditional metrics surrounding a clinical trial. We were looking for a true partner that could embody the key elements of our vision and culture."

All of the potential candidates performed very well when it came to the capabilities of execution metrics and the ability to source. Since Takeda had worked with all of the CROs in the past, it was also familiar with the capabilities of each company. But Nabulsi notes he was looking for a CRO that would view the relationship as a true partnership.

"We did not want them to think about trial results as simply a deliverable metric," states Nabulsi. "Drug discovery is about patients. That was important to us, and we wanted a partner who valued it as well. For us, trials are not just about getting a molecule approved. They are about connecting a medicine we discover with a patient in need. That was one of our key elements."

TAKE CARE OF OUR EMPLOYEES

People were another key element for Takeda. The new partnering agreement would transfer approximately 300 people from Takeda's offices in the U.S. and Europe and approximately 140 in Japan to the CRO partner. Takeda asked all the candidates to provide details (including examples) of how they would manage that transfer. Takeda would be transferring some of its most talented and passionate individuals, and Nabulsi wanted to know how the selected CRO would create opportunities for them.

"We wanted to be sure they were looked at as important members of the team and not just as resources that would be lumped into some efficiency metric," he notes. "We wanted them to remain a part of this strategic relationship, and we wanted to ensure that they would remain engaged with our projects as long as we had a sufficient workflow available."

On its first contact with the selected CROs, Takeda explained, at a very high level, what it was hoping to achieve. The company used specific bullet points to explain what it wanted out of the relationship. "It was literally just a concept — nothing more than that," says Nabulsi. "We asked them to go away and come back to us with an idea or a vision. We wanted to see something that would help us understand what they would help us get out of the relationship. Then we had meetings in our offices, Deerfield, IL, in particular, where they came in with their initial plans. We asked them to come in with free-flowing ideas that would help us understand their vision."

"WE DID NOT WANT THEM [POTENTIAL CROs] TO THINK ABOUT TRIAL RESULTS AS SIMPLY A DELIVERABLE METRIC."

Dr. Azmi Nabulsi
Deputy CMSO, Head, Strategic & Professional Affairs

IF YOU'RE THE BEST, CONVINCE ME

Nabulsi notes that he did not request any specific type of presentation. Companies were asked to send whoever they felt would be relevant to the relationship and explain their plan. The disparity in presentations was actually quite surprising. All of the potential partners showed up with senior executives. Some teams even included the company's CEO. While some of the presentations were structured and had an engineered feel to them (including detailed slides with parameters, metrics, and promised deliverables), others brought in a team of high-level executives who just sat and talked about what they hoped to accomplish with the partnership. Although more informal, these conversations were still very deep.

Although the feel of the presentations varied, he notes that was expected because of the lack of formal guidance provided. "For the first engagement, we were far more interested in how we connected with each other," he says. "We wanted to know if they had an appreciation for what we were trying to accomplish. This was not a bid process. It was an attempt to see if we had enough in common to form the basis of a successful trusting partnership."

After that process was complete, Takeda moved on to the next step, which was asking the CROs to present a couple of key elements of their plan. There were generally two or three of those meetings, and they were more in-depth than the initial meetings. More individuals were involved, and technical details were provided on outsourcing and procurement. Takeda personnel asked a lot of specific questions, and the CROs were also permitted to ask questions in response. This allowed Takeda to gain additional insights into the plan being presented.

TAKEDA IS COMING TO VISIT

The next phase of the selection process involved visiting the CROs in their offices and meeting their people. Each CRO was asked, "If we move forward with this partnership, who are the people on your side who will be involved?" The company then had meetings with those individuals to see if the two sides would click. The discussions at each meeting became more technical and more operational. There were also more questions along the line of, "What would you do in this case?" Or "How would you handle this situation?" Nabulsi notes that each discussion became more in-depth than the previous.

During this entire vetting process, the CRO rankings maintained by Takeda changed dramatically. Nabulsi emphasizes again that these changes were not entirely due to technical elements. Those elements were certainly important and were weighted accordingly. But equally important were the feelings of Takeda personnel about how the two companies could work together as partners, and Nabulsi believes that factor, more than any other, helped make the decision easy.

"Simply looking at measured deliverables might be sufficient when signing a two- or three-year deal," says Nabulsi. "But we were interested in a long-term relationship. Therefore we needed to see if each partner had the ability to commit to and invest in that type of relationship. This is something we had never done before, so having an experienced partner beside us on the journey was paramount. We also needed them to work with us to create the model we wanted, as opposed to trying to force us into a model they wanted because they had done it before. They had to be open to saying, 'We have never done this before, but we think it is a great idea and are willing to discuss how we can do it together.'"

THEY ARE NOT A CRO

If you ask Nabulsi about outsourcing to a CRO, he will quickly correct you and describe the relationship as a partnership. In fact, in internal discussions, Takeda does not even refer to PRA as a CRO. He notes it is part of the culture they are trying to build between the two companies.

"I hear people say, 'My company has contracted with a CRO,'" says Nabulsi. "We do not consider this to be outsourcing, and we do not see them as an external company. They are a partner. With the recently announced creation of a Takeda-PRA joint venture in Japan, we have more than 400 employees moving from one loca-

tion to another. We are trying to make that message very clear."

Since culture is important to the partnership, determining the culture of the candidates was important, and the site visits were a critical component of the selection process.

Takeda took a close look at the employees: How they worked, how they interacted with each other, how they expressed themselves, how they communicated with Takeda personnel, and how natural they were in those conversations. Employees were also asked about how they dealt with internal transformations and prior mergers and acquisitions.

"Having that communication with employees, whether it was formal or informal, gave us a good sense of their internal culture," says Nabulsi. "They allowed us to see how they think, what is important to them, and what they value in partners. That helped us to determine what it would be like to work with them as colleagues and partners and how they work and interact. We wanted to know how they motivate their employees and how they develop their internal talent. We wanted to be sure that our people would be working in the right environment and would be motivated to work there."

STILL MORE WORK TO DO

Although Nabulsi is very pleased with the relationship thus far, he adds there is a lot more work to be done. Much of that centers on execution of the partnership and taking the vision of the two companies and making it a reality. He is looking forward to seeing that execution come to fruition, and is confident it will be done. "We believe this is a model other companies will want to emulate," he adds.

CROs often complain that a sponsor will spend months deciding on the best partner and then proceed to tell them how to do their job. Nabulsi notes that will not be the case with this relationship and is a part of the execution challenge. Takeda's goal from the outset was to improve operational excellence, and that entails ensuring the best practices of both companies are used in its clinical trials.

"We are very open to using the processes of our chosen partner," adds Nabulsi. "That is the best way to achieve operational excellence. Moving forward we will look at the expertise PRA brings to the table and move forward with what we together think is best. We let them know we were not coming into this relationship insisting that they use the processes and procedures we had in place. We believe that will be a very positive outcome of this partnership."

Measuring The Health Of CRO-Sponsor Relationships

LAURIE HALLORAN, BSN, MS

As the majority of clinical trials involve external collaborations, healthy relationships between a sponsor and its partners (e.g., CROs) cannot be overemphasized. In this article, much of what we will discuss pertains to the relationship between a CRO and its sponsor, the life science company. However, any company providing a contracted service to a sponsor will find there are valuable lessons to be learned regarding relationship management.

The market for CROs continues to consolidate, and many of these businesses are becoming as large as or even larger than the companies they serve. But no matter what size the sponsor (nor whether it's public or private), shareholder return from profits of newly marketed products is always going to be a primary business goal. CROs, on the other hand, are service providers focused on selling their time. This difference between these entities sometimes creates a conundrum of imperfectly aligned business objectives that can be a major source of problems if not managed from the onset.

While small or early-clinical-stage companies are required to minimize their fixed costs through outsourcing, midsize and large companies seek more strategic relationships and single-source providers to tackle the challenges associated with both speedy program execution and cost containment. Thus, when collaborating with CROs, life science companies face complex challenges that obviously can impact clinical outcomes. However, there are a number of proactive approaches to take in working with CROs to manage relationships, align objectives, and reap benefits for both parties.

MITIGATING CRO-LIFE SCIENCE COMPANY RELATIONSHIP CHALLENGES

The health of these relationships is critical and is an often underlying cause of project failure if not attended to. If the arrangement is initiated and managed well, there is a better likelihood of identifying risks and preventing problems down the road. These relationships require continuous effort on both sides, and that effort is not to be underestimated.

A relationship catastrophe is often seeded in the early days of an outsourcing decision. For example, recently we were involved with a company that had an executive mandate to outsource with a midsize pharma company. They needed to become more efficient after two products were beaten to market by competitors. Since their end-of-year deadline was handed down from the C-level, there was a scramble to choose and begin a complex relationship that the majority of the development team had never encountered. Red flags were everywhere. Rushing the start of a new outsourcing model without the necessary support and insights can lead to missteps in the process. Instead, it is imperative a company allocate — up front — the appropriate time needed to learn how to work efficiently in a new outsourcing paradigm.

AVOID MISSTEPS WITH MASTER SERVICE AGREEMENTS

Contractual documents are almost impossible to draft without understanding future challenges. When sponsor companies elect to move to strategic outsourcing, many thorny issues arise when hastily negotiated Master Service Agreements (MSAs) are executed. This is a crit-

ical time to set expectations appropriately, yet it's an opportunity that is frequently rushed with limited consideration for both a transparent exchange and appropriate checks and balances that favor both parties.

To avoid problems when setting strategic expectations:

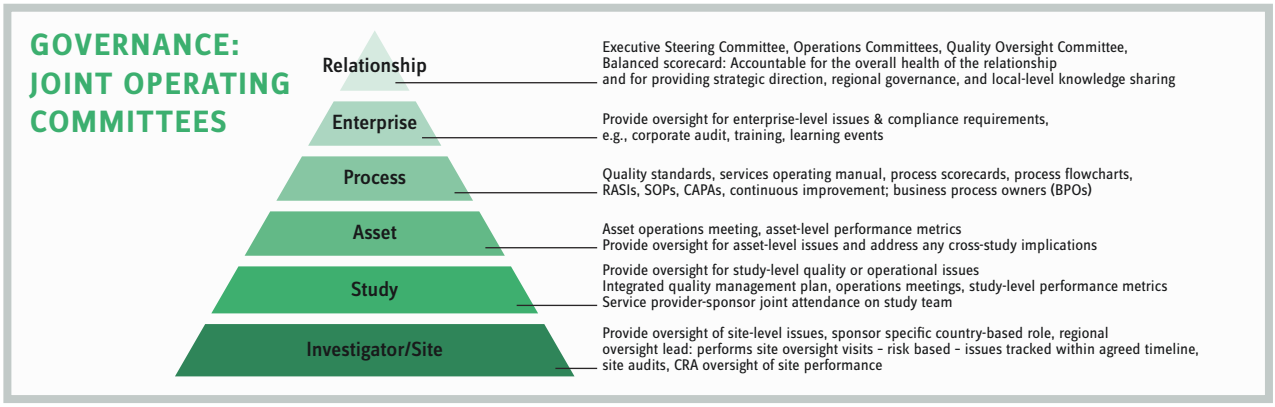
- **Create two or three deliverables for each program that are directly linked to the MSA.** This helps clarify how to share risk, especially with change orders, quality issues, and staff transitions.
- **Implement a fixed-price program approach.** This will contain the scope creep that can threaten to derail early programs and sour the relationship.
- **Determine the goals of the partnership and communicate them.** Don't assume that efficiencies in time, cost, and quality will all be achievable. There is always a tradeoff, and it is imperative to implement a shared-operational model.
- **Agree upon customer-service metrics.** Partner-health performance metrics must be decided upon for key stakeholders who may be affected by the partnership. The partnership must continue to improve over time in order for it to continue.

TAKING LESSONS FROM STRATEGIC PARTNERSHIPS

In a single-source scenario — or any outsourcing relationship — strong and involved governance, a shared operational model, and regular reconciliation on scope are must-haves for a healthy relationship. And all of this should be handled at the beginning of the relationship.

Early on you should also provide notification of key staff transitions and shared costs for transition time above a certain level of program size. Regardless of project size, clearly describe who all the participants are and the roles of joint-operating committees (see graphic on next page), which should meet quarterly. Include the ability for the sponsor to escalate issues to an executive level within the CRO and specify who the counterparts are at each of the partners.

At the onset of the relationship, determine a time-



line and define a set of metrics with options to refine the metrics at predefined milestones. KPIs should be tailored to the critical aspects of your programs and shaped by:

- Determining how metrics will be available — ideally in a program that is continuously updated to maintain visibility.
- Appointing stable relationship managers to actively recognize when KPIs need refinement and manage the adoption of new metrics.

However, two issues can arise with data identification:

- Study teams frequently want a deluge of data that is not valuable for identifying areas of improvement or best practices.
- Inconsistency in what data teams want ensures that systemic relationship issues cannot be identified across multiple programs. In midsize or large sponsor companies this can require several FTEs when most of the portfolio is outsourced.

The value of metrics relies on the underlying data used to generate them. If you have 100 studies in your portfolio, what percentage of them should be performing on track? One colleague who has managed this successfully says it should be a minimum of 95 percent. Gaining this insight is difficult, and the governance at a middle level needs to determine an appropriate trigger point above which remediation is needed.

Another major requirement for healthy collaboration is retaining the interest level. From our conversations with sponsors who outsource as a business strategy, the bigger the spend, the higher the interest on the part of the CRO. This presents a major challenge to small sponsors who don't have a lot of money to spend each year with a large CRO.

Our clients say that if large CROs think a long-term engagement will form, they will invest the time to build the relationship. Smaller companies acknowledge that they require more assistance than larger companies, and that is often a lot for the CRO to handle, but it illustrates the need for early, attentive, and transparent communication at an executive level. This level of communication should be mandated in every relationship, considering it is the biggest source of frustration for sponsors.

In earlier stages of development, it may be beneficial to go with a smaller CRO and then shift to a larger CRO for later stages where the global reach is a better fit to conduct large programs. This isn't ideal for most companies to have to change relationships in a program, but it underscores the need for the sponsor to conduct development planning practices regularly.

From the sponsor's viewpoint, one of the biggest disappointments in outsourcing is how the day to day work gets done, documented, overseen, and communicated. Every CRO project manager has likely encountered a sponsor manager who micromanages and criticizes every activity and deliverable. There need to be efficient communication channels between subject matter experts to build shared operational models that don't bottleneck through the project managers. For example, at one client, we recently encountered four different groups that all thought they were responsible for managing the CRO, creating a lot of miscommunication.

At the outset, it is important to realign your business processes to cover the changes that outsourcing brings. Many companies that embark on a significant outsourcing change have SOPS that are irrelevant to the business model.

The most effective way to measure the health of the relationship is to look to the individuals and teams to do it. Surveys are a tried-and-true method but should be performed by both the sponsor and vendor as well as with any type of contracted service provider and investigators.

In summary, professional relationships are the most loyal and yield the greatest results when they are treated as personal relationships. Managing and checking-in on the relationship are the keys to fostering a strong partnership, regardless of shareholder return. L

LAURIE HALLORAN, BSN, MS is the president and CEO of Halloran Consulting Group, which she founded in 1998. She currently lectures at the Boston University School of Medicine and the Tufts Center for Drug Development Post-Graduate program.

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Strategic Partnerships: What Companies Want, What They Are Getting, And What It Means

LAKSHMI SUNDAR

Sponsors and CROs have entered into more and more strategic partnerships during the past decade to achieve a range of shared and distinct goals. Yet, while many of the partnerships were unveiled with media fanfare, there is a shortage of analyses of what both sides want out of relationships, the extent to which their expectations are being met, and what this means for the future of clinical outsourcing. To address this gap, The Avoca Group followed our 2011 survey on strategic partnerships with a new canvassing of sponsors and providers.

Responses to the 2011 survey are testament to the then-nascent nature of strategic partnerships. The survey revealed significant disconnects in sponsor and provider perceptions of the dynamics and strengths of strategic partnerships. Approximately half of sponsors said strategic partnerships were failing to meet their expectations in priority areas such as the quality of deliverables, sparing of internal resources, and cost savings. Providers viewed their relationships more favorably, although as many as one-third of respondents expressed dissatisfaction in some key areas.

Given the long-term nature and complexity of strategic partnerships, the presence of problems and disconnects in the early years of relationships was broadly unsurprising. The questions now are whether sponsors and CROs have worked through these challenges and remain committed to strategic partnerships. To answer these and other questions, Avoca polled 130 professionals from 79 individual sponsor companies and 84 professionals from 41 providers about their experiences and expectations for the future.

DRIVERS OF INCREASED OUTSOURCING

The challenges sponsors faced in 2011 have not put them off outsourcing. In 2011, respondents said 65 percent of their clinical development spend went to providers. Today, the proportion is 69 percent. Large and midsize CROs are capturing 50 cents of every $1 spent with providers, with the rest being shared among smaller CROs, technical providers, and academic groups.

A little more than one-third of clinical outsourcing spend goes to strategic partners. The number of sponsors in such relationships is on the rise. Today, 62 percent of sponsors are in strategic partnerships, an increase of 27 percent over 2011.

The data also shows a shift in the number of partnerships individual sponsors are in. While the first wave of strategic partnerships was dominated by sponsors funneling clinical development work to a few CROs, companies have since brought on additional providers. This trend is reflected in a 79 percent jump in the number of sponsors with four or more strategic partners. The number of providers with four or more strategic partners has risen since 2011, too.

Taken together, the responses show a continued, intensifying commitment to outsourcing and the strategic partnership model in particular. Small and specialty biopharma companies, which made up one-third of the sponsors polled, are outsourcing to retain lean business models while working to deliver clinical data capable of attracting a partner, an acquirer, or investors. Larger companies are increasingly looking to such small biopharma firms for pipeline candidates and are themselves outsourcing to reduce fixed costs while accessing expertise.

WHAT COMPANIES WANT FROM PARTNERSHIPS

These general motivations for outsourcing are reflected in the reasons sponsors give for entering into stra-

tegic partnerships. Approximately half of respondents to the 2016 survey listed reduced costs as a primary objective for strategic partnerships, making it the most commonly sought goal from such relationships. The 2011 survey had the same finding.

Sponsors also have retained an interest in improving internal staff efficiency, but their motivations in other areas have changed. In 2016, fewer sponsors listed less tangible benefits, such as accessing operational expertise and improving quality, as priorities.

> *"A little more than one-third of clinical outsourcing spend goes to strategic partners."*

Provider motivations have changed, too. In 2016, nearly half of respondents listed meeting the needs of current customers as a primary goal of strategic partnerships. This marks a 41 percent increase over 2011. That goal has replaced increased profits near the top of the list of priorities. Approximately one-fifth of providers listed improved profitability as a priority in 2016, down from 36 percent in 2011. While some priorities have changed in some areas, for most providers, increased business stability remains the most important priority of strategic partnerships.

WHAT COMPANIES GET FROM PARTNERSHIPS

At least 84 percent of respondents said partnerships met or exceeded their expectations for four of their top five objectives, including the key goals of meeting customer needs and increasing business stability. The outlier is increased profitability. More than one-quarter of providers said partnerships were failing to meet expectations in this area, despite a double-digit percentage increase in levels of satisfaction over 2011. Only one-third of providers said profitability expectations were met in the first year of relationships, reflecting the up-front investments in staffing and other adjustments CROs have to make to gear up for partnerships.

While many providers are having to wait a year or more to achieve their goals, more and more of them are doing so in the end. The proportion of providers whose expectations are being met rose by 10 percentage points or more in five areas between 2011 and 2016. The areas include primary objectives such as improved quality.

Sponsors are also increasingly satisfied with the performance of their partnerships, although on the whole they remain less content than providers. The 2016 poll found double-digit percentage increases in the proportion of sponsors whose expectations are being met in three areas, including high priorities such as reducing contracting and improving the quality of deliverables. However, the survey also found a double-digit decline in satisfaction with access to high-quality personnel.

The 2016 survey also found continued dissatisfaction with the ability of strategic partnerships to meet sponsors' top priority: cost savings. In 2016, 45 percent of sponsors said their expectations in this area were being met or exceeded, compared with 48 percent in 2011.

Poor performance in this one area mars a dataset that otherwise suggests the disconnect in sponsor and provider perceptions has narrowed, and satisfaction with the outsourcing model overall is on the rise.

THE HEALTH OF CLINICAL OUTSOURCING TODAY

The increase in the proportion of strategic partnerships that are meeting sponsor and provider expectations is part of a broader trend that suggests the health of clinical outsourcing in general, and close alliances in particular, is improving. While disconnects persist, the gap is narrowing, and the survey suggests strategic partnerships are contributing to these improvements.

The disconnect between sponsor and provider satisfaction with relationships is narrower among companies in strategic partnerships than for outsourcing in general. There is reason to believe this finding will persist. Notably, the longer a sponsor is in a strategic partnership, the more likely it is to be satisfied with the relationship, the work delivered, and value for money. Only satisfaction with quality delivered remains flat over time.

Buoyed by their experiences, more than half of sponsors plan to make more use of strategic partnerships over the next five years. Sponsors that are satisfied with their current relationships and the quality they deliver are most likely to plan to make greater use of partnerships. Most providers also anticipate greater use of the model.

The survey data suggests these new and existing partnerships will face persistent problems, such as an inability to meet sponsor expectations of cost savings and the failure for quality to improve over time. Yet overall the trends identified from 2011 to 2016 show strategic partnering is in better health today.

LAKSHMI SUNDAR is VP of strategy and development at The Avoca Group.

Experiential Data Sheds Light On The CRO Selection Process

REBECCA MCAVOY

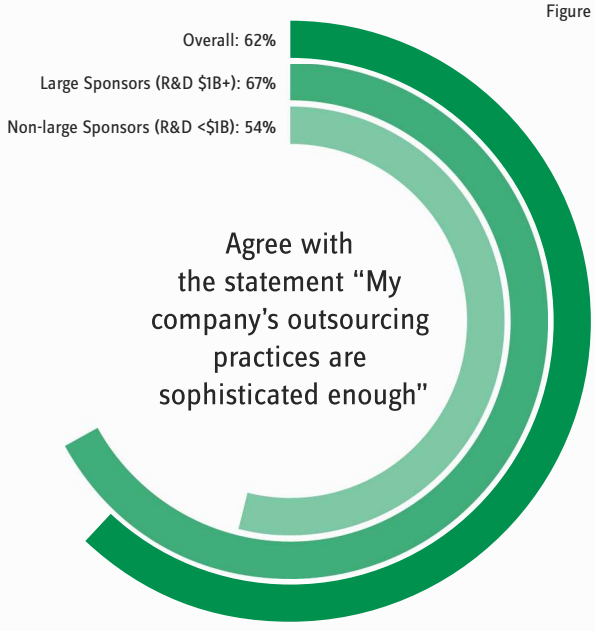
Picking the best service provider for your unique outsourced clinical development work can sometimes feel like playing pin the tail on the donkey. Don a blindfold. Spin around. Wander with no clear sense of direction toward your target. Luckily, it doesn't have to be this way. Data and tools are available to better inform your provider search. Industry Standard Research (ISR), a full-service market research provider to the pharma and pharma services industries, has collected information from outsourcing decision makers via an online survey regarding their selection and evaluation of CROs.

Respondents relay the attributes they consider critical when selecting a service provider and then rate, along the same dimensions, the performance of providers with which they have recently worked. Using selection-driver data and provider-performance ratings in tandem enables sponsors to make an educated outsourcing decision.

As part of this research, ISR gathered respondents' opinions on the sophistication of their companies' outsourcing practices (Figure 1). Overall, 62 percent of decision makers believe their company employs sufficiently sophisticated outsourcing practices. Not surprisingly, those from large sponsors (annual R&D spend $1B+) are generally more pleased with their company's level of outsourcing sophistication than are those at smaller companies where nearly half of respondents do not consider their company's outsourcing practices to be sophisticated enough.

One method to enhance outsourcing sophistication is for decision makers to determine the qualities that are most important for their provider to exhibit before broaching provider evaluation and selection. Beginning with defined attribute goals will narrow the search and make it easier to find a well-matched provider. ISR's research offers the industry's viewpoint on selection driver importance across several different scenarios: 1) choosing a provider from a preferred provider list, 2) choosing a provider that is not on the preferred provider list, and 3) choosing a provider in the absence of a preferred list. Those with preferred provider agreements (PPAs) convey what is important when choosing a provider from their preferred list as well as what drivers are important when choosing a provider that is not on their company's list.

Figure 1



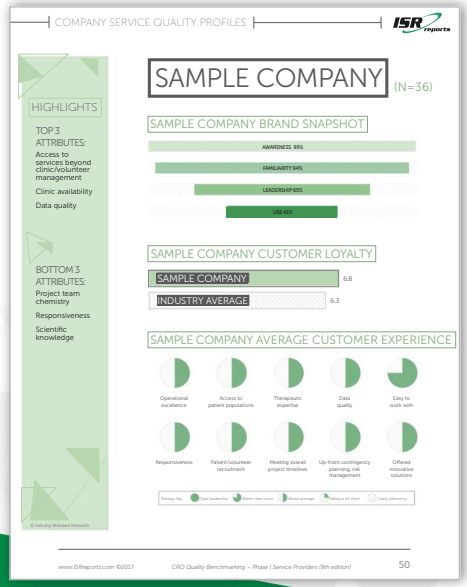
Source: Industry Standard Research, CRO Quality Benchmarking Report Suite (2017)

ACCESS CRO PERFORMANCE EVALUATIONS

ISR reports

Smarter questions ∴ Smarter answers

CRO quality evaluations for Phase I, II/III, and IV outsourcing—updated for 2017



CRO LEADERSHIP AWARDS2017

DISCOVER THE DATA BEHIND THE AWARDS

- *Consumer Reports*-style analysis of CRO performance
- A benchmark of contract research organizations on their performance specific to Phases I, II/III, and IV related services
- Performance ratings from hundreds of CRO users

THE LATEST IN TRENDS & TECHNOLOGY REPORTS

- Phase I Study Trends and Market Outlook (2016-2020)
- 2017 Edition of the CRO Market Size Projections: 2016-2021
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TOP PHASE 2/3 SELECTION ATTRIBUTES BY DECISION-MAKING SCENARIO

Top Phase 2/3 Attribute	Choosing among preferred providers	Choosing a provider not on the preferred list	No preferred provider list
Operational excellence	1	1	1
Prior positive experience with service provider	2	4	2
Therapeutic expertise	3	3	3
Global footprint	4	5	6
Project manager quality	5	(15)	4
Experience with similar study types	6	2	5
Patient recruitment strategy	7	(9)	(8)
Low cost	(9)	6	(12)
Easy to work with	(17)	(13)	7
Network of sites/investigators	(11)	7	(18)

Figure 2 Source: Industry Standard Research, CRO Quality Benchmarking Report Suite (2017)

Figure 2 contains the seven most important attributes for each decision-making scenario when selecting a Phase 2/3 provider. For comparison and completeness, ranks for attributes that are in the top seven attributes for one scenario but not for others are shown in parentheses. Several interesting findings come to light when selection attributes are approached in this manner:

- *Operational excellence* is king. There's no getting around it. This attribute is the most important selection driver regardless of the decision-making scenario. Providers need to prove that they are operationally proficient to win sponsors' trust.
- Also universally important are *Prior positive experience with service provider* and *Therapeutic expertise*, ranking between slots 2 and 4 in each scenario.
- *Experience with similar study types* is important for all scenarios but carries the most weight when sponsors are choosing a provider that is not among their preferred providers. One reason why sponsors may choose to use a provider outside of their list is for a specialized study type with which their preferred providers might not have much experience. Ranking *Experience with similar study types* so highly is likely due to the search for providers with a specific expertise or skillset.
- *Easy to work with* has its highest importance ranking when a company does not have preferred providers. When a sponsor selects a company as a preferred provider, there are many decision points that can be universally agreed upon and then do not have to be discussed or negotiated at the start of every project. Furthermore, as sponsors tend to use their preferred providers again and again, efficiencies in the working relationships can be realized. However, when there are no PPAs in place, details must be hammered out anew for each project, and there may not be a pre-established working relationship. These factors may play large roles in why those with no preferred provider agreements place more importance on being *Easy to work with*.

For decision makers whose companies have sophisticated outsourcing processes, using peer-based data can assist in evaluating CROs. Those at larger, more sophisticated sponsor organizations often focus much of their work on a set of preferred providers but may need to consider a broader set of CROs when preferred providers are not available.

Utilizing data from peers' experiences can arm decision makers with the knowledge to make more educated decisions throughout the outsourcing process. The data and resources are there. All you need to do is lift the blindfold.

Survey Methodology: ISR's CRO Quality Benchmarking research is conducted annually via an online survey. For the 2017 CRO Awards data, more than 60 service providers were evaluated on over 25 different performance metrics. Research participants were recruited from biopharma and medical device companies of all sizes and are screened for decision-making influence and authority when it comes to working with CROs. **Respondents evaluate only companies with which they have worked on an outsourced project within the past 18 months.** This level of qualification ensures that quality ratings come from actual involvement with a business and that companies identified as leaders are backed by experiential data.

List Of Winners
Page 26-32
Company Profiles
Page 33-38

CRO LEADERSHIP AWARDS 2017

Life Science Leader's pharmaceutical and biopharmaceutical executive-level readers have told us about their struggles in efficiently vetting potential CRO partners. In response to this input, *Life Science Leader* developed the CRO Leadership Awards.

The awards are based on Industry Standard Research's "Contract Research Organization Quality Benchmarking" annual online survey, which included 72 CROs that were evaluated on 27 different performance metrics. Research participants were recruited from biopharmaceutical companies of all sizes and were screened for decision-making influence and authority when it comes to working with contract research organizations. Respondents evaluate only companies with which they have worked on an outsourced project within the past 18 months. This level of qualification ensures that quality ratings come from actual involvement with a business and that companies identified as leaders are backed by experiential data. CROs have an opportunity to win these awards in up to three groups of outsourcing respondents — Big Pharma, Small Pharma, and Overall (combined Big and Small Pharma).

WHAT ARE THE AWARDS?

ISR survey participants were asked to provide an expectation rating for each CRO they have worked with in the past 18 months. Points were then totaled for a combined score for each attribute, and a composite score for each core category was determined. Winning CROs were determined when comparing their overall score vs. the competitive set.

To learn more about ISR's industry reports or customized research, or to be included in future CRO Quality Benchmarking annual surveys, visit isrreports.com or contact ISR at (919) 301-0106.

PRESENTED BY:

Life Science Leader

RESEARCH CONDUCTED BY:

ISR reports

Smarter questions ∴ Smarter answers

CRO LEADERSHIP AWARDS 2017 CAPABILITIES

- Access to "unique" tests, machines, equipment
- Access to a broad range of services beyond clinic / volunteer management
- Access to patient populations
- Offered innovative solutions
- Patient / volunteer recruitment
- Speed of site start-up
- Technology for real-time access to data
- Breadth of services
- Global footprint
- Network of sites / investigators
- Patient recruitment strategy
- Speed of site / investigator recruitment

CAPABILITIES

TOP PERFORMERS

OVERALL

Rho
Vince & Associates Clinical Research
SGS
Lambda Therapeutic Research
DaVita Clinical Research
BioPharma Services Inc.
Quotient Clinical

BIG PHARMA

SGS
DaVita Clinical Research

SMALL PHARMA

Worldwide Clinical Trials
Celerion
Lambda Therapeutic Research
Rho
DaVita Clinical Research
SGS
Pharm-Olam International

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

Celerion
Pharm-Olam International
Worldwide Clinical Trials
TKL Research
BIOTRIAL
Bioclinica
Covance
Quintiles
WCCT Global
QPS Holdings LLC

BIG PHARMA

Lambda Therapeutic Research
Quotient Clinical
BIOTRIAL
TKL Research
INC Research
Bioclinica
Quintiles
Covance
Celerion
InVentiv Health
PPD

SMALL PHARMA

Bioclinica
Quintiles
Covance
Medpace

MET CUSTOMER EXPECTATIONS

OVERALL

PPD
UBC
PAREXEL
INC Research
Duke Clinical Research Institute
NAMSA
InVentiv Health
ICON
Medpace
Tata
PRA
Frontage Laboratories
Accenture

BIG PHARMA

Duke Clinical Research Institute
Worldwide Clinical Trials
PAREXEL
QPS Holdings LLC
ICON
Premier Research
PRA
Tata
Eurofins Scientific

SMALL PHARMA

Algorithme Pharma
PAREXEL
PRA
PPD

The terms "Small Pharma" and "Big Pharma" pertain to the outsourcing respondents, not the winners. "Overall" is a combination of Big and Small Pharma.

CRO LEADERSHIP AWARDS 2017
COMPATIBILITY

- Easy to work with
- Project team chemistry
- Responsiveness
- Timely project communications

COMPATIBILITY

TOP PERFORMERS

OVERALL
Rho
Pharm-Olam International
Vince & Associates Clinical Research
BioPharma Services Inc.
SGS
DaVita Clinical Research
Celerion
Quotient Clinical
BIOTRIAL
Medpace
Lambda Therapeutic Research
Duke Clinical Research Institute

BIG PHARMA
BIOTRIAL
SGS

SMALL PHARMA
Pharm-Olam International
Rho
Worldwide Clinical Trials
Medpace
Celerion
DaVita Clinical Research
SGS
Lambda Therapeutic Research

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL
TKL Research
Accenture
Worldwide Clinical Trials
INC Research
QPS Holdings LLC
NAMSA
WCCT Global

BIG PHARMA
Lambda Therapeutic Research
DaVita Clinical Research
TKL Research
Quotient Clinical
Duke Clinical Research Institute
INC Research
InVentiv Health
Celerion
Accenture
Medpace
PPD

SMALL PHARMA
Bioclinica
Chiltern

MET CUSTOMER EXPECTATIONS

OVERALL
InVentiv Health
Bioclinica
PPD
Covance
UBC
Quintiles
PRA
Chiltern
PAREXEL
Tata
Frontage Laboratories
Eurofins Scientific
ICON
Novotech

BIG PHARMA
Covance
Quintiles
QPS Holdings LLC
PAREXEL
PRA
Tata
Bioclinica
Worldwide Clinical Trials
ICON
Premier Research

SMALL PHARMA
Eurofins Scientific
PRA
Quintiles
ICON
PPD
Covance
INC Research

CRO LEADERSHIP AWARDS 2017 EXPERTISE

- Experience of the Phase I unit's lead investigator
- Local market / regulatory knowledge
- Operational excellence
- Scientific knowledge
- Therapeutic expertise
- Study design expertise

EXPERTISE

TOP PERFORMERS

OVERALL

Rho
Vince & Associates Clinical Research
DaVita Clinical Research
BioPharma Services Inc.
SGS
BIOTRIAL
Duke Clinical Research Institute

BIG PHARMA

DaVita Clinical Research
SGS

SMALL PHARMA

DaVita Clinical Research
Rho
Celerion
Bioclinica
Worldwide Clinical Trials
Lambda Therapeutic Research
Algorithme Pharma

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

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Medpace
InVentiv Health
Worldwide Clinical Trials
Accenture
Covance
Celerion
PPD

SMALL PHARMA

Pharm-Olam International
Medpace
Quintiles
SGS

MET CUSTOMER EXPECTATIONS

OVERALL

PPD
NAMSA
INC Research
PAREXEL
TKL Research
InVentiv Health
Algorithme Pharma
PRA
US Oncology
ICON
Frontage Laboratories
Novotech
Eurofins Scientific

BIG PHARMA

QPS Holdings LLC
Bioclinica
PAREXEL
TKL Research
PRA
ICON
Mapi
Tata

SMALL PHARMA

PPD
Covance
Eurofins Scientific
PAREXEL
PRA
ICON

The terms "Small Pharma" and "Big Pharma" pertain to the outsourcing respondents, not the winners. "Overall" is a combination of Big and Small Pharma.

CRO LEADERSHIP AWARDS 2017 QUALITY

- Data quality
- Project manager quality
- CRA quality

QUALITY

TOP PERFORMERS

OVERALL

Pharm-Olam International
Vince & Associates Clinical Research
Rho
SGS
Lambda Therapeutic Research
BIOTRIAL
DaVita Clinical Research

BIG PHARMA

SGS
BIOTRIAL

SMALL PHARMA

Pharm-Olam International
DaVita Clinical Research
SGS
Rho
Worldwide Clinical Trials
Lambda Therapeutic Research
Medpace
Celerion

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

BioPharma Services Inc.
TKL Research
Quotient Clinical
Duke Clinical Research Institute
UBC
Medpace
Worldwide Clinical Trials
QPS Holdings LLC
Accenture
Bioclinica
INC Research
Covance
Tata

BIG PHARMA

Lambda Therapeutic Research
Quotient Clinical
Duke Clinical Research Institute
TKL Research
INC Research
DaVita Clinical Research
Accenture
Covance
Medpace
PPD
Tata

SMALL PHARMA

Bioclinica
Eurofins Scientific

MET CUSTOMER EXPECTATIONS

OVERALL

Quintiles
PPD
WCCT Global
NAMSA
Celerion
PRA
US Oncology
ICON
PAREXEL
InVentiv Health
Frontage Laboratories

BIG PHARMA

Quintiles
Bioclinica
InVentiv Health
PAREXEL
QPS Holdings LLC
ICON
PRA
Worldwide Clinical Trials

SMALL PHARMA

PRA
Quintiles
Chiltern
Covance

CRO LEADERSHIP AWARDS 2017 RELIABILITY

- Meeting overall project timelines
- Operational excellence
- Minimizing staff turnover

RELIABLITY

TOP PERFORMERS

OVERALL

Rho
Vince & Associates Clinical Research
Pharm-Olam International
BioPharma Services Inc.
SGS
DaVita Clinical Research
Celerion
Quotient Clinical
Lambda Therapeutic Research

BIG PHARMA

BIOTRIAL
SGS
Lambda Therapeutic Research
Quotient Clinical
DaVita Clinical Research

SMALL PHARMA

Celerion
Pharm-Olam International
Rho
Worldwide Clinical Trials
DaVita Clinical Research
Medpace
SGS
Lambda Therapeutic Research

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

BIOTRIAL
Worldwide Clinical Trials
Medpace
WCCT Global
QPS Holdings LLC
Duke Clinical Research Institute
TKL Research
Accenture
NAMSA

BIG PHARMA

TKL Research
Duke Clinical Research Institute
InVentiv Health
Celerion
Accenture
Worldwide Clinical Trials
PPD

SMALL PHARMA

Bioclinica
Algorithme Pharma

MET CUSTOMER EXPECTATIONS

OVERALL

Quintiles
PPD
Tata
Covance
UBC
Bioclinica
Chiltern
InVentiv Health
US Oncology

BIG PHARMA

Quintiles
Covance
Medpace
INC Research
Tata
QPS Holdings LLC
Chiltern
ICON
PAREXEL

SMALL PHARMA

Eurofins Scientific
Quintiles

The terms "Small Pharma" and "Big Pharma" pertain to the outsourcing respondents, not the winners. "Overall" is a combination of Big and Small Pharma.

CRO LEADERSHIP AWARDS

INDIVIDUAL ATTRIBUTE AWARDS

The Individual Attribute Awards were developed as a result of many conversations we have had with the readers of *Life Science Leader*. These conversations uncovered common attributes that sponsor companies identified as being imperative when choosing a supplier and deciding to continue doing business with a supplier.

They were often referred to as the ever-important "intangibles" a supplier brings to the table. Outside of the cover metrics of capabilities, compatibility, expertise, quality, and reliability, these attributes were what our readers identified as being the most important, and as such, we felt it was important to share the data with other sponsor companies.

DATA QUALITY

TOP PERFORMERS

Rho
Vince & Associates Clinical Research
SGS
Pharm-Olam International
UBC
DaVita Clinical Research

EXCEEDED CUSTOMER EXPECTATIONS

Lambda Therapeutic Research
BIOTRIAL
Quotient Clinical
Accenture
BioPharma Services Inc.
Bioclinica
Tata
Worldwide Clinical Trials
Duke Clinical Research Institute
Covance
Quintiles
TKL Research

MEETING PROJECT TIMELINES

TOP PERFORMERS

Rho
SGS
Vince & Associates Clinical Research
Quotient Clinical
BioPharma Services Inc.
Lambda Therapeutic Research
Celerion
BIOTRIAL
TKL Research
DaVita Clinical Research
Accenture

EXCEEDED CUSTOMER EXPECTATIONS

Pharm-Olam International
WCCT Global
Duke Clinical Research Institute
Medpace
QPS Holdings
NAMSA
Bioclinica
Worldwide Clinical Trials
UBC
Quintiles

OFFERED INNOVATIVE SOLUTIONS

TOP PERFORMERS

Vince & Associates Clinical Research
DaVita Clinical Research
Quotient Clinical
SGS
Rho
Algorithme Pharma
BioPharma Services Inc.
Bioclinica

EXCEEDED CUSTOMER EXPECTATIONS

Eurofins Scientific
BIOTRIAL
Pharm-Olam International
UBC
TKL Research
Accenture
Duke Clinical Research Institute
Lambda Therapeutic Research
QPS Holdings
Celerion
Worldwide Clinical Trials
NAMSA
Quintiles
WCCT Global
Frontage Laboratories

CRO LEADERSHIP AWARDS

INDIVIDUAL ATTRIBUTE AWARDS

OPERATIONAL EXCELLENCE

TOP PERFORMERS

Pharm-Olam International
Vince & Associates Clinical Research
DaVita Clinical Research
Rho
BioPharma Services Inc.
Accenture
Celerion
SGS
Quotient Clinical
Lambda Therapeutic Research
Worldwide Clinical Trials

EXCEEDED CUSTOMER EXPECTATIONS

Medpace
NAMSA
BIOTRIAL
QPS Holdings
WCCT Global
Quintiles
Tata
PPD
Bioclinica
Duke Clinical Research Institute
Covance

RESPONSIVENESS

TOP PERFORMERS

Vince & Associates Clinical Research
BioPharma Services Inc.
Rho
Pharm-Olam International
Medpace
SGS
Quotient Clinical
Duke Clinical Research Institute
BIOTRIAL
DaVita Clinical Research
Celerion

EXCEEDED CUSTOMER EXPECTATIONS

Lambda Therapeutic Research
Worldwide Clinical Trials
NAMSA
Premier Research
UBC
INC Research
Accenture
Bioclinica
WCCT Global
InVentiv Health
Frontage Laboratories
PPD

TECHNOLOGY FOR ACCESS TO DATA

TOP PERFORMERS

Rho
SGS
BioPharma Services Inc.
DaVita Clinical Research

EXCEEDED CUSTOMER EXPECTATIONS

Pharm-Olam International
Vince & Associates Clinical Research
Tata
BIOTRIAL
Quotient Clinical
Bioclinica
Worldwide Clinical Trials
Quintiles
WCCT Global
PAREXEL
Lambda Therapeutic Research
Celerion
Duke Clinical Research Institute
Covance

CATEGORIES WON:

Algorithme Pharma

Québec, Canada
www.altasciences.com

Phone: 450-973-6077
Contact: Cathy Konidas
Email: ckonidas@altasciences.com
Key locations: Laval, Québec, Canada

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical, Phase 1, Phase 2

MAIN SERVICE AREAS:
Lab, Full Service Clinical

SERVICES & CAPABILITIES: healthy normal volunteers, spec. populations, POC, adapt. design, SAD/MAD, bioavailability & bioequivalence, PK/PD, dose ranging, biosimilars, lg & sm molecule bioanalysis, data mgmt., biostatistics, reg. support, proj. mgmt

THERAPEUTIC AREAS: allergy, cardiovascular, CNS, cognitive testing, dermatology, diabetes, electroencephalography, gastrointestinal, hematology, hepatitis, metab. disorders, nephrology, obesity, ophthalmology, pain & inflamm., psychiatry, postmenopausal women, pulmonary, women's health, vaccines, others upon request

INDIVIDUAL ATTRIBUTE AWARDS: offered innovative solutions

CHRIS PERKIN
CEO

"These awards recognize our team's ongoing dedication to going above and beyond to address the ever-evolving and increasingly complex needs of sponsors, while maintaining a high level of participant engagement and safety. I couldn't be more proud!"

CATEGORIES WON:

Celerion

Lincoln, Nebraska
www.celerion.com

Phone: 402-476-2811
Contact: David Maya
Email: david.maya@celerion.com
Key locations: Montréal, Québec, Canada

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical, Phase 1, Phase 2

MAIN SERVICE AREAS:
Lab, Full Service Clinical

SERVICES & CAPABILITIES: First-In-Human, clinical POC & patient dose response studies, cardiovascular safety & clinical pharmacology research supporting product labeling. Other services include statistics, PK/PD analysis, & small/large molecule bioanalytical services.

THERAPEUTIC AREAS: respiratory, metabolic disease, NAFLD/NASH, vaccines, renal & hepatic impairment, oncology, autoimmune disorders, cardiovascular, ophthalmology & personalized medicine

INDIVIDUAL ATTRIBUTE AWARDS: meeting overall project, offered innovative solutions, operational excellence, responsiveness, technology for real-time access to data

SUSAN THORNTON
President & CEO

"For over 40 years Celerion has been at the forefront of early clinical research. Winning the CRO Leadership award across all five categories highlights the value we consistently deliver to our clients. Our extensive experience and expertise in managing complex early phase studies in healthy volunteers and patients enables us to provide unique insights for successful clinical development programs. We would like to thank our clients for this recognition and their continued partnership with Celerion."

CATEGORIES WON:

Chiltern

Wilmington, North Carolina
www.chiltern.com

Phone: 910-338-4760
Contact: Sara Davis
Email: sara.davis@chiltern.com
Key locations: Slough, Berkshire, UK; Wilmington, NC, USA; Bangalore, India

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical, Phase 1, Phase 2, Phase 3

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: clinical development, medical & scientific affairs, data & analysis, pharmacovigilance, strategic regulatory, medical device & diagnostics, strategic development, strategic service provision

THERAPEUTIC AREAS: cardiovascular, dermatology, endocrinology & metabolism, gastroenterology, immunology & rheumatology, infectious disease & vaccines, neuroscience, oncology, ophthalmology, orthopedics, radiology & nuclear medicine, respiratory, women's health

JIM ESINHART, PHD
CEO

"At Chiltern, our clients are always at the center of what we do. Our Designed Around You® philosophy and our personal relationships allow us to work in collaboration to deliver quality clinical development solutions every day. It is our mission to provide our clients a better, more personalized experience than any other CRO, because the harder we work, the better the quality of life we help provide for patients around the world."

CATEGORIES WON:

Covance Inc.

Princeton, New Jersey
www.covance.com

Phone: 609-452-4440
Contact: Sue Maynard
Email: susan.maynard@covance.com
Key locations: Princeton, NJ; Indianapolis, IN; Madison, WI; Leeds, UK; Shanghai; Singapore

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Pre-Clinical, Clinical, Phase 1, Phase 2, Phase 3
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

MAIN SERVICE AREAS:
Lab, Pre-Clinical, Full Service Clinical

SERVICES & CAPABILITIES: Covance Marketplace (partnering network), early phase dev. solutions (Preclinical to FIH/POC), genomics, companion diagnostics, biomarkers, informatics, market access svcs, mobile health, patient access & provider services, regulatory, risk-based monitoring, sample mgmt.

THERAPEUTIC AREAS: asthma, allergy, autoimmune, inflamm., cardiovascular, CNS, dermatology, gastroenterology, gen. medicine, hematology, infect. disease, metabolic, endocrine, musculoskeletal, nephrology, nutrition, oncology/immuno-oncology, ophthalmology, pulmonary/respiratory, rep. health, rheumatology, urology

INDIVIDUAL ATTRIBUTE AWARDS: data quality, operational excellence, technology for real-time access to data

JOHN RATLIFF
CEO

"At Covance, we are united by our strong sense of purpose at this time of extraordinary advances in healthcare. We bring clients a unique perspective, combining our breadth of capabilities from research to real world, with deep scientific expertise. We are enabled by award-winning technology and informed by leading data and analytics. Above all, we are driven to improve health and improve lives, inspiring us to deliver more for clients. We truly appreciate this recognition."

CATEGORIES WON:

DaVita Clinical Research

Minneapolis, Minnesota
www.davitaclinicalresearch.com

Phone: 612-852-7000
Contact: Kevin Goudreau
Email: kevin.goudreau@davita.com
Key locations: Minneapolis, MN; Denver, CO; Los Angeles, CA; Las Vegas, NV; Houston, TX; New York, NY; Colorado Springs, CA; Dusseldorf, Germany

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical, Phase 1, Phase 2, Phase 3

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: full-service Phase 1-2a trials, including medical writing & data mgmt.; Phase 2b-4 clinical trials & site network; de-identified patient datasets, including EHRs, claims, Rx & lab data

THERAPEUTIC AREAS: nephrology, diabetes, cardiovascular disease, pulmonology, oncology, autoimmune disorders, renal impairment, hepatic impairment, healthy normal volunteers, first-in-human, dose-ranging, ADME, internal medicine

INDIVIDUAL ATTRIBUTE AWARDS: data quality, meeting overall project timelines, offered innovative solutions, operational excellence, responsiveness, technology for real-time access to data

AMY YOUN
VP & General Manager

"As a wholly owned subsidiary of a multi-specialty healthcare provider, DCR is unique in the expertise and insights we can offer our clients. Our large network of clinical sites, broad therapeutic reach, and de-identified patient datasets enable us to provide data-driven feasibility and rapid site start-up. We have capabilities across the spectrum of drug development, including two hospital-based clinical pharmacology units, and I'm delighted our clients are seeing the value we can provide them."

CATEGORIES WON:

Duke Clinical Research Institute

Durham, North Carolina
www.dcri.org

Phone: 919-668-8700
Contact: Matt Gross
Email: matt.gross@duke.edu
Key locations: Durham, North Carolina

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical, Phase 1, Phase 2, Phase 3

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: The DCRI conducts multinational clinical trials, manages patient registries, and performs outcomes research. DCRI research spans disciplines from pediatrics to geriatrics, primary care to subspecialty medicine, and genomics to proteomics.

THERAPEUTIC AREAS: cardiovascular, respiratory, neuroscience, infectious diseases, gastroenterology, hepatology, musculoskeletal, pediatrics

INDIVIDUAL ATTRIBUTE AWARDS: data quality, meeting overall project timelines, offered innovative solutions, operational excellence, responsiveness, technology for real-time access to data

ERIC PETERSON
Executive Director

"It's an honor to be recognized again for the work we are doing to make tomorrow better than today for patients around the world. This award is evidence that our peers understand the value of the unique perspective the DCRI brings to the most vital healthcare questions of the day."

CATEGORIES WON:

Eurofins Scientific

Kraainem, Belgium
www.eurofins.com

Phone: 717-656-2300
Contact: Dirk Bontridder
Email: pharma@eurofins.com
Key locations: Lancaster, PA; San Diego, CA; St. Charles, MO; Toronto, Canada; Munich, Germany; Milan, Italy; Sydney, Australia; Tokyo, Japan

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Pre-Clinical, Clinical, Phase 1, Phase 2, Phase 3
Formulated Drug Production: Dosage Form Production, Packaging, Logistics

MAIN SERVICE AREAS:
Lab, Pre-Clinical, Full Service Clinical

SERVICES & CAPABILITIES: Eurofins provides pharma discovery, preclinical, early development, central laboratory, cGMP product testing, bioanalytical, genomic, medical device and human safety testing services.

THERAPEUTIC AREAS: Eurofins Biopharma Services supports all therapeutic areas within the Bio/Pharma and Medical Device industries.

INDIVIDUAL ATTRIBUTE AWARDS: offered innovative solutions

GILLES MARTIN
CEO

"To receive the CRO Leadership Award for the quality category is a great achievement. Eurofins' dedication to quality is embedded in our values, our mission, and the work we perform around the world every day. We are pleased that the bio/pharmaceutical industry continues to recognize Eurofins as a leader in delivering quality testing results."

CATEGORIES WON:

INC Research

Raleigh, North Carolina
www.increasearch.com

Phone: 919-876-9300
Contact: Michael Kleppinger
Email: michael.kleppinger@increasearch.com
Key locations: Raleigh, NC; Camberley, UK; Singapore; Austin, TX; Toronto, Canada; Beijing, China; Mexico City, Mexico; Tokyo, Japan

DRUG LIFE CYCLE STAGES:
Research & Development: Phase 1, Phase 2, Phase 3

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: Full range of Phase I to Phase IV clinical development services for the biopharmaceutical and medical device industries.

THERAPEUTIC AREAS: cardiovascular, CNS analgesia, CNS neurology, CNS psychiatry, endocrinology, gastroenterology/hepatology, hematology, immunology & inflammation, infectious disease, oncology, ophthalmology, respiratory, women's health, cross-functional solutions, biosimilars, medical devices, orphan & rare diseases, pediatrics

INDIVIDUAL ATTRIBUTE AWARDS:
responsiveness

ALISTAIR MACDONALD
CEO

"INC Research continues to perform well in awards based on relationships and quality because of the undying commitment of our global workforce to deliver exceptional results for our customers. The CRO Leadership Awards are further validation that our customers recognize the value we bring to every relationship as INC's Trusted Process and commitment to providing accredited, passionate and skilled professionals ensure that we provide the very best processes, procedures and expertise to all projects."

CATEGORIES WON:

inVentiv Health

Boston, Massachusetts
www.inventivhealth.com

Phone: 800-416-0555
Contact: Gregory Skalicky
Email: clinical.information@inventivhealth.com
Key locations: Boston, MA; Princeton, NJ; Blue Bell, PA; New York, NY; Maidenhead, England; Seoul, Korea; Shanghai, China; Tokyo, Japan

DRUG LIFE CYCLE STAGES:
Research & Development: Pre-Clinical, Clinical, Phase 1, Phase 2, Phase 3

MAIN SERVICE AREAS:
Lab, Full Service Clinical

SERVICES & CAPABILITIES: full service, biostatistics, monitoring, data mgmt., drug safety & pharmacovigilance, feasibility & study start-up, staffing, late-stage, market research, medical & scientific affairs, medical writing, patient recruitment, risk mgmt., statistical programming

THERAPEUTIC AREAS: Therapeutically aligned project teams. Expertise across all areas including biosimilars, cardiovascular, dermatology, endocrine & metabolic, gastroenterology, hematology, infectious disease, immunology & inflammation, neuroscience, oncology, pediatrics, rare disease, respiratory, women's health.

INDIVIDUAL ATTRIBUTE AWARDS:
responsiveness

MICHAEL J. MCKELVEY, PH.D
EVP, inVentiv Health & President, inVentiv Health Clinical

"inVentiv Health is honored be recognized with a Life Science Leadership Award. This recognition is an indication that our comprehensive outsourcing model – combining a leading full-service CRO with the industry's only Contract Commercial Organization (CCO) – provides value-enhancing services to clients navigating a complex environment. It also celebrates our employees who apply deep therapeutic and operational expertise to create better, faster, and smarter ways to help biopharmaceutical clients accelerate the delivery of therapies to market."

CATEGORIES WON:

NAMSA

Toledo, Ohio
www.namsa.com

Phone: 866-666-9455
Contact: Leah Davidson
Email: ldavidson@namsa.com
Key locations: Toldeo, OH; Minneapolis, MN; Irvine, CA; Seoul, Korea; Tokyo, Japan; Shanghai, China; Beijing, China; Lyon, France; Frankfurt, Germany; Selby, United Kingdom; Petach Tikva, Israel

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Pre-Clinical, Clinical, Phase 1, Phase 2, Phase 3
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production

MAIN SERVICE AREAS:
Lab, Pre-Clinical, Full Service Clinical

SERVICES & CAPABILITIES: Regulatory consulting, pre-clinical testing services, medical device testing, clinical services

THERAPEUTIC AREAS: anesthesia/respiratory, cardiology, dental, dermal wound care, diabetic, diagnostic imaging, ear/nose/throat, gastroenterology, general/plastic surgery, IVD/companion diagnostics, neurosurgery, OB/GYN, oncology, opthalmology, orthopedics, peripheral vascular, regenerative medicine

INDIVIDUAL ATTRIBUTE AWARDS: meeting overall project timelines, offered innovative solutions, operational excellence, responsiveness

JOHN GORSKI
President & CEO

"NAMSA has a laser-like focus on accelerating medical device development and commercialization efforts for thousands of clients worldwide. For over 50 years, our experienced teams have consistently delivered superior results throughout the full spectrum of product development - testing, clinical, and regulatory - time and time again. By combining the knowledge of our dedicated associates with our translational research approach, customers not only achieve clinical endpoints more quickly, but they also make more effective key commercialization decisions that lead to success."

CATEGORIES WON:

Pharm-Olam International

Houston, Texas
www.pharm-olam.com

Phone: 713-559-7900
Contact: Mark Eberhardt
Email: mark.eberhardt@pharm-olam.com
Key locations: Houston, TX; Ascot, UK

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical, Phase 1, Phase 2, Phase 3

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: A multinational CRO offering comprehensive services to the pharma, biotech, and device industries. From Phase I to IV, we focus on delivering high-quality data, targeted enrollment & meeting projected timelines.

THERAPEUTIC AREAS: cardiovascular, dermatology, device, endocrinology, gastroenterology, gynecology, hematology, infectious disease, neurology, oncology, ophthalmology, pediatrics, respiratory/allergy, rheumatology/inflammation, urology/nephrology

INDIVIDUAL ATTRIBUTE AWARDS: data quality, meeting overall project timelines, offered innovative solutions, operational excellence, responsiveness, technology for real-time access to data

DR. ZEV MUNK
Chairman of the Board

"We're honored to be recognized by the CRO Leadership Awards in each of the five core award categories again. These awards are a validation of the dedication, flexibility, commitment to quality, and sponsor-first focus that our team strives for day-in and day-out. We appreciate that clinical trials are a significant investment for our sponsors, and we believe our mission – 'Helping Create a Healthier World' – reflects their goals and ambitions."

CATEGORIES WON:

PPD

Wilmington North Carolina
www.ppdi.com

Phone: 910-251-0081
Contact: PPD Business Development
Email: ppdinfo@ppdi.com
Key locations: Wilmington, NC; Research Triangle, NC; Madison, WI; Austin, TX; Richmond, VA; Europe; China; Japan

DRUG LIFE CYCLE STAGES:
Research & Development: Pre-Clinical, Clinical, Phase 1, Phase 2, Phase 3

MAIN SERVICE AREAS:
Lab, Full Service Clinical

SERVICES & CAPABILITIES: Phase I, Phase II-IIIb, post-approval. Bioanalytical, GMP, central, and vaccine sciences labs, biomarker services. Consulting services: product development, biosimilars, adaptive trial design, pediatrics, rare diseases, cardiovascular outcomes, medical devices.

THERAPEUTIC AREAS: cardiovascular, critical care, dermatology, endocrine & metabolics, gastroenterology, hematology & oncology, immunology, infectious diseases, neuroscience, ophthalmology, rare diseases, respiratory, urology

INDIVIDUAL ATTRIBUTE AWARDS: operational excellence, responsiveness

DAVID SIMMONS
Chairman & CEO

"PPD is committed to accelerating the generation of evidence necessary for our customers to bring life-changing therapies to society. Pharmaceutical and biotechnology clients can rely on our expertise and tailored, quality-first services across Phase I-IV and post-approval research, with integrated and comprehensive laboratory services and industry leadership in site and patient relationships. Our strategically expanded service offerings help ensure our clients' evolving needs are met with precision and high quality across the drug development continuum."

CATEGORIES WON:

QPS Holdings LLC

Newark, Delaware
www.qps.com

Phone: 512-350-2827
Contact: Lily Rosa
Email: info@qps.com
Key locations: Newark, DE; Springfield, MO; Fargo, ND; Research Triangle Park, NC; Hollywood, FL; South Miami, FL; Groningen, The Netherlands; Graz, Austria; Hyderabad, India; Barcelona, Spain; Taipei, Taiwan

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Pre-Clinical, Clinical, Phase 1, Phase 2

MAIN SERVICE AREAS:
Lab, Pre-Clinical, Full Service Clinical

SERVICES & CAPABILITIES: neuropharmacology, DMPK, toxicology, bioanalysis, translational medicine, dermal & transdermal, clinical development

THERAPEUTIC AREAS: neurodegenerative (Alzheimer's, Parkinson's, Huntington's, MS, ALS), CNS (depression, schizophrenia, ADHD), respiratory (asthma, COPD, allergy), metabolic (obesity, T2DM), inflammatory (RA, psoriasis), viral (HIV, HCV, HBV), dermatology, oncology, & many more diseases

INDIVIDUAL ATTRIBUTE AWARDS: meeting overall project timelines, offered innovative solutions, operational excellence

BENJAMIN CHIEN
Chairman, President & CEO

"I am extremely gratified that out of 72 candidate companies, QPS has received a CRO Leadership Award in all five categories: Capabilities, Compatibility, Expertise, Quality, and Reliability. We strive to provide the most nimble, anticipatory, customer-centric and scientifically rigorous service possible. On behalf of our dedicated team, I thank the decision-makers at Pharma and Biopharma companies, both Big and Small, who rated QPS so highly."

CATEGORIES WON:

Rho

Durham, North Carolina
www.rhoworld.com

Phone: 919-408-8000
Contact: Katie McElveen
Email: katie_mcelveen@rhoworld.com
Key locations: Chapel Hill, NC

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical, Phase 1, Phase 2, Phase 3

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: We are a full-service CRO providing services across the drug development process including regulatory strategy, regulatory submissions, biometrics, project management, clinical operations, medical monitoring, & pharmacovigilance.

THERAPEUTIC AREAS: CNS, psychiatric disorders, pain management, orphan products & rare diseases, respiratory diseases, ophthalmology, dental, pediatrics

INDIVIDUAL ATTRIBUTE AWARDS: data quality, meeting overall project timelines, offered innovative solutions, operational excellence, responsiveness, technology for real-time access to data

LAURA HELMS REECE
CEO

"We are honored to be recognized again with this prestigious award. It reflects our mission to deliver an unrivaled customer experience through research excellence and is a testament to the dedication and hard work of our outstanding employees."

CATEGORIES WON:

SGS

Mechelen, Belgium
www.sgs.com/cro

Phone: 301-556-0881
Contact: Ron Baker
Email: ron.baker@sgs.com
Key locations: Antwerp, Belgium; Mechelen, Belgium; Germantown, Washington DC; Geneva, Switzerland; Poitiers, France

DRUG LIFE CYCLE STAGES:
Research & Development: Pre-Clinical, Clinical, Phase 1, Phase 2, Phase 3
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production

MAIN SERVICE AREAS:
Lab, Full Service Clinical

SERVICES & CAPABILITIES: Clinical: FIH, viral challenge testing, early phase in patients trials, sputum induction, cerebrospinal fluid sampling. Biometrics EDC, CDISC compliant. Laboratory: biologics characterization, biosafety testing, bioanalysis, quality control.

THERAPEUTIC AREAS: infectious diseases, oncology, respiratory, CNS, cardiovascular

INDIVIDUAL ATTRIBUTE AWARDS: data quality, meeting overall project timelines, offered innovative solutions, operational excellence, responsiveness, technology for real-time access to data

LUC BRAEKEN
Global Dir. Biometrics & Medical Affairs - Business Unit Manager

"As a result of over 35 years of experience and investment in clinical research, SGS is proud to be recognized by the following CRO leadership awards: Capabilities, Compatibility, Expertise, Quality, and Reliability. Our mission is to support biopharm and pharma companies in developing their drug candidates, with a personalized approach so they can be confident in the safety and efficacy of their products. Our best reward is our client satisfaction."

CATEGORIES WON:

UBC

Blue Bell, Pennsylvania
www.ubc.com

Phone: 314-684-5112
Contact: Christine Portell
Email: cportell@express-scripts.com
Key locations: Blue Bell, PA; St. Louis, MO; London, England; Geneva, Switzerland; Memphis, TN; Kansas City, MO; McLean, VA; Montreal, Canada

DRUG LIFE CYCLE STAGES:
Research & Development: Phase 2, Phase 3

SERVICES & CAPABILITIES: Clinical trial implementation & management, patient recruitment, peri and postapproval studies, registries, & value demonstration studies. We focus on helping biopharmaceutical sponsors generate real-world evidence to obtain regulatory approval.

THERAPEUTIC AREAS: oncology, cardiology/vascular, neurology, endocrinology. gastroenterology, immunology & inflammation, infectious diseases, pulmonary/respiratory, urology, dermatology, rheumatology, women's health

INDIVIDUAL ATTRIBUTE AWARDS: data quality, meeting overall project timelines, offered innovative solutions, responsiveness

PATRICK LINDSAY
President

"At UBC, we believe experience matters. Our tenured scientists and operational experts work closely together to address pharma's challenges. We deliver a comprehensive, integrated view of clinical product, patient, and population safety - beginning in clinical development and lasting through a product's full lifecycle. The quality of our services is rooted in a strong commitment to our clients. Together, we can help them reach their goals while making medicines safer and more accessible to patients."

CATEGORIES WON:

Vince & Associates Clinical Research

Overland Park, Kansas
www.vinceandassociates.com

Phone: 913-696-1601
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Key locations: Overland Park, KS

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical, Phase 1 Phase 2

MAIN SERVICE AREAS:
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SERVICES & CAPABILITIES: Phase I-II, healthy normal volunteers, special populations, POC, adapt. design, FIH, SAD/MAD, bioavailability & bioequivalence, PK/PD, dose ranging, food effect, QT/QTc, biosimilars, human abuse liability/substance abuse

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INDIVIDUAL ATTRIBUTE AWARDS: data quality, meeting overall project timelines, offered innovative solutions, operational excellence, responsiveness, technology for real-time access to data

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CEO & Medical Director

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Morrisville, North Carolina
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Phone: 919-674-2900
Contact: Bill Hirschman
Email: william.hirschman@worldwide.com
Key locations: North America, South America, Europe, Russia, Asia

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MAIN SERVICE AREAS:
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SERVICES & CAPABILITIES: Worldwide Clinical Trials is one of the world's leading, full-service contract research organizations. We deliver fully integrated clinical development and bioanalytical services, extending from first-in-human through phase IV studies.

THERAPEUTIC AREAS: We help sponsors move from discovery into clinical development and commercialization across a range of therapeutic areas, including neuroscience, cardiovascular diseases, immune-mediated inflammatory disorders (IMID), & rare diseases.

INDIVIDUAL ATTRIBUTE AWARDS: data quality, meeting overall project timelines, offered innovative solutions, operational excellence, responsiveness, technology for real-time access to data

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Finding The Right CRO For Rare Disease Trials

ED MISETA Chief Editor, Clinical Leader @EdClinical

CRO selection is a challenge for every company outsourcing clinical trials. When the trial you are about to launch is for a rare genetic disease and has 30 patients spread across several countries and continents, the challenges are multiplied.

This was the situation for Cerenis Therapeutics, which recently launched a Phase 3 trial for patients having very low levels of high-density lipoprotein (HDL), also known as good cholesterol. The low levels of HDL make patients prone to cardiovascular events such as stroke or heart attack. The Cerenis medicine, CER-001, attempts to mimic HDL, allowing the body to rid itself of cholesterol.

In this Q&A, Cerenis founder and CEO Jean-Louis Dasseux discusses the challenges of rare disease trial and why the selection of the right CRO is so important to the success of the trial.

ED MISETA: In rare disease trials, does the CRO selection process become more difficult?

JEAN-LOUIS DASSEUX: I think so. Since this is the first time a trial is addressing a rare ailment, there is really no CRO on the planet with experience dealing with this patient population. That means the experience is generally coming from the sponsor. Therefore, the role of the CRO becomes more critical. They have to be the liaison between the pharma company and the sites and patients and are responsible for transferring that experience from one group to the other. They also have to be experts in the conduct of a trial. It's a lot of responsibility for them.

MISETA: Have there been any situations where you requested that someone at the CRO be removed from a study?

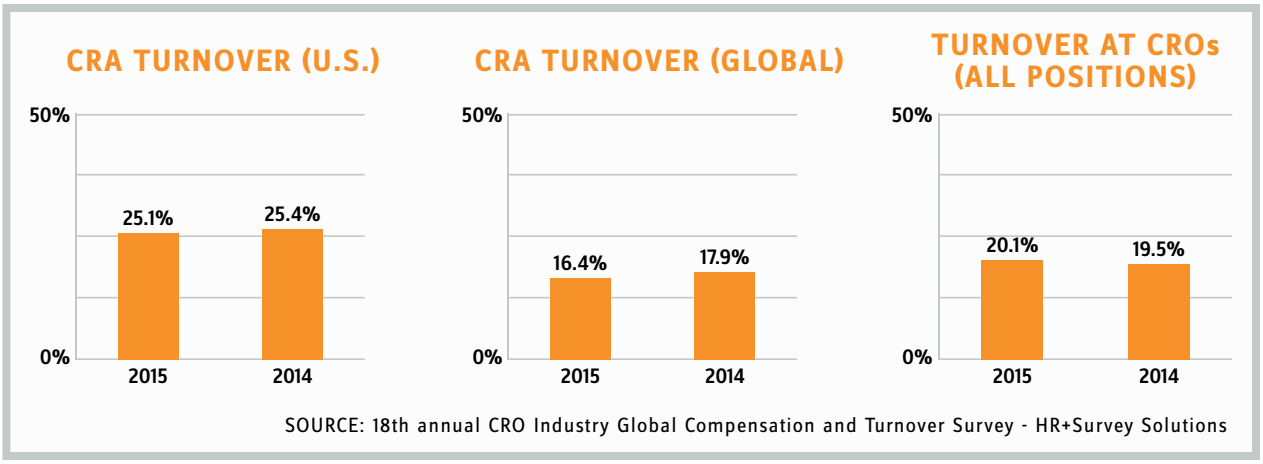
DASSEUX: That was necessary once, and we felt the individual at the CRO was simply not the right person for the trial. In that case, the concern was the individual's technical knowledge of trials and how to handle a study where good clinical practice and adhering to requirements set by regulators was critical. But passion is also something we look for in a CRO.

We need to have emotion, to have people who are dedicated to the study. Above all else, this is a human adventure. What is more important to me than the size of the CRO is choosing the one we feel will be most engaged in the study. Some of the larger CROs are not interested in a study involving 30 patients. As a result, we have struggled to find appropriate CROs and will often look for ones that are local to the areas where we are conducting the studies. I believe interactions with the CRO are essential to this relationship, and we are deeply involved with them. We will generally have interactions with them on a daily basis.

MISETA: When you believe a personnel change is necessary, that must be a difficult conversation. Is it usually done at a high level?

DASSEUX: Yes. We try to be a responsible company, and we certainly don't want anyone to take something like that personally. What we will try to do is go to upper management within the company and let them know we believe an issue exists with one person involved in the trial, or that we feel there is a dedication issue. I tell them that a different type of person might be more appropriate and ask if they can resolve it internally.

We are certainly not looking to be confrontational in any way. If we think a change is necessary, we want to handle it in the most delicate manner possible. In a



SOURCE: 18th annual CRO Industry Global Compensation and Turnover Survey - HR+Survey Solutions

rare disease trial, we expect a great deal of commitment from all of our partners. That often includes a large time commitment on the part of key individuals. These are all good people, but sometimes that required commitment is just not possible due to personal reasons or family needs.

In those cases, we will reach out to the person to see if they can perform better. If we still see some issues, then we will go to upper management at the CRO to see if they can help us find a solution.

MISETA: Many sponsors also complain about personnel changes at the CRO. Is this ever an issue for you?

DASSEUX: Yes, definitely. I think it is a problem for the entire industry. You have one team leader at the beginning of a study, and then three months later you are working with someone else. We all know this is due to the pressure and challenges these folks face, and the fact is they are always jumping from one CRO to another. It's a difficult situation for everyone. We will always explain to the CRO the difficult nature of rare disease trials and will request that they assign us someone who is stable and able to stick with the trial until the very end. We always stress the importance of that relationship, because we feel it is critical to the trial.

MISETA: Everyone always wants the CRO's "A-Team," but we know it is not possible for every company to get it.

DASSEUX: Exactly. And not being a Big Pharma company, we do not have the deep pockets that allow us to always get our way. We also do not have a huge internal team that can help with the transition from one team leader to another. For that reason we have to be deeply involved in all of the activities being handled by the CRO and have regular meetings with them. That is just an additional cost of running a rare disease indication clinical trial.

MISETA: Are there rewards to that type of model as well?

DASSEUX: Yes. The other side of the coin is there are many CROs that share our philosophy. We now have many of them calling us and saying they would love to work with our company because of these relationships we develop. The value we get from these human relationships will definitely work both ways.

The ideal CRO for us is an organization that is passionate about the disease and excited to be working on a trial that has the potential to become a breakthrough therapy that will save the lives of patients. With many CROs, we find they value in working closely with our team and not some faceless department within a much bigger organization.

MISETA: Do you find there is an appreciation on the part of the CRO when they feel you are treating them the same way you want to be treated?

DASSEUX: Yes, and that is a key point. At the end of the day we are all people, and drug discovery is definitely a human adventure, as I mentioned earlier. Every little step we take has a big impact on the overall success of the trial. This includes patients being motivated and not being made to feel they are guinea pigs. Physicians have to understand the value the trial brings to their patients. Then consider all the other partners involved — the CROs, suppliers, carriers, and those teams involved in all of the different countries. We all have to be on the same page, working together, and personally involved with the effort. If one of those links fails, the trial will not be a success. Everyone has to be committed to working together as a team.

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