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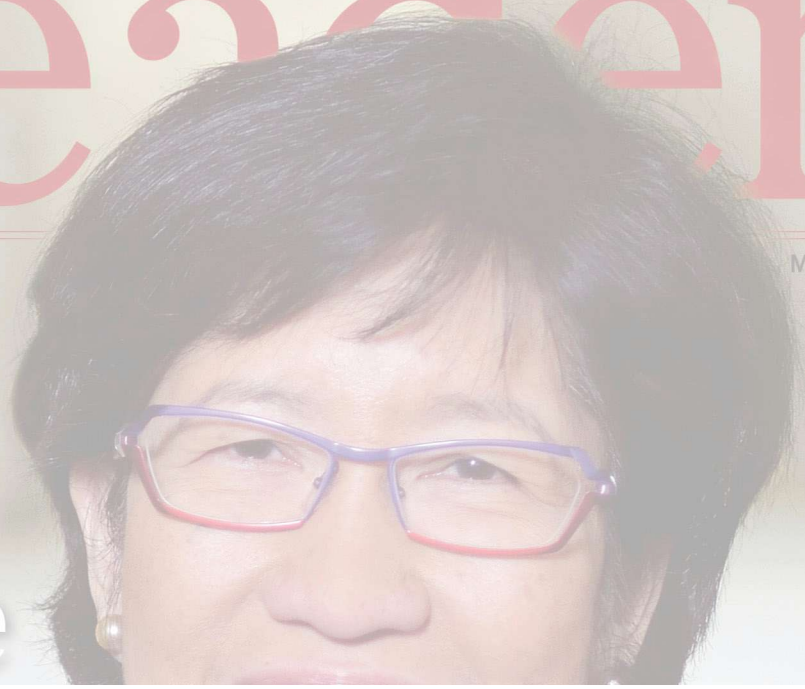

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SVP and global head of clinical operations and external collaborations, Roche

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CROs Will Play A Critical Role
In The Future Of Drug Development

ED MISETA Executive Editor, Clinical Leader

There are a couple of differences you will see in this 2016 installment of our annual CRO Supplement. The first, which you may have already noticed, is the cover. In the past, these covers have featured an image that seemed to best illustrate a concept we addressed in the issue. That was very different from the typical cover you see on *Life Science Leader*, which always features a prominent executive from the pharma and biotech industries. Beginning with this CRO supplement, we will feature a clinical executive whom you will likely know and recognize.

I was thrilled when Dr. Corsee Sanders agreed to be the first executive to grace the cover of this issue. I first spoke with her last fall while preparing an article for our December Industry Outlook. Her comments and insights into the future of clinical trials were refreshing and insightful. Part of that had to do with her background, which is in math and statistics, rather than pharmaceutical development. This gives her a different perspective on how we should be gathering, analyzing, and using the data gathered from trials.

In this article, Sanders discusses a challenge she faced when stepping into the role of global head of clinical operations at Roche. As a statistician, she was uncomfortable with decisions based on information that employees knew from experience but couldn't back up with hard data. In addition, it seemed the same data sets could exist in different systems, and yet yield different results. One of her current projects attempts to bring those systems together under one umbrella, with a single dashboard providing executives with the answers they need. What does she see as the benefits of such an endeavor? You can read about it beginning on page 6.

If you're a regular reader of *Life Science Leader*, then you also know our editorial focus is on executives at bio and pharma companies rather than technology or service providers. But an article in this issue examining the CRO of the future features an executive from Merck, as well as leaders from three contract research firms. When I heard these gentlemen speak at the Disruptive Innovations conference last fall, I knew the discussion belonged in this issue. Some of the topics covered in the article include the growth of CROs, standardization, and the challenges faced by CROs and what they will need to do to continue to be a vendor of choice for sponsors.

With the way clinical trials are changing, it should come as no surprise that sponsors expect their CROs to adapt to those changes. It wasn't too long ago that many pharma companies were not dealing with patient-centricity issue, risk-based monitoring, adaptive trials, electronic files and records, and wearable technologies. While many of these changes have the potential to fundamentally transform clinical trials, they also have the potential to disrupt operations within companies.

In the past, a CRO might be expected to perform a task requested by a client. Today, those same clients are expecting the CRO to come to them with innovative ideas and new methods of incorporating novel technologies. Rob DiCicco, VP of clinical innovation and digital platforms at GSK, recently summed up this expectation for me. "I am always interested in what the CRO is able to bring to the table in terms of know-how," he says. "We are always looking for ideas that can disrupt the company. We celebrate the fact that there are companies that know things we don't. When a CRO can bring innovative knowledge and expertise to the relationship, it helps both of us to get to a better place, and we welcome their ideas that will help us come up with the best possible plan."

I hope the insights in this issue will help *you* come up with better clinical plans, as well.

Life Science Leader
MAY 2016 CRO SUPPLEMENT

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CORSEE SANDERS, PH.D.
SVP and global head of clinical operations and external collaborations at Roche

Corsee Sanders is a statistician by training, having earned both a bachelor's degree and Ph.D. in statistics. Unlike many in similar positions, she did not grow up in a clinical trials environment, having only joined the clinical operations team at Roche four years ago, moving over from a position as the global head of biometrics. However, as the SVP and global head of clinical operations and external collaborations, her new role in overseeing trials with Roche is key to the success of her company's studies.

When working in the biometrics space, Sanders was used to having clean, manageable, and analyzable data that could be used for modeling and predictions to assess and raise a program's probability of success. She has found that in clinical operations she also has to deal with a lot of data, not just about patients, but about the clinical trials themselves.

"The data tells us how many trials are running, where they are, who is running them, how long it takes to run a clinical trial in certain countries, and information on how long it takes to recruit a patient in a specific area. All of this information is extremely quantifiable and valuable to the conduct of a study."

But her experience working in clinical operations also has allowed her to look beyond the data. She has found that a lot of the information used in the decision-making process is not data captured in a system or in an evaluable format. It is information and knowledge that exists in the minds of the team members. While there is certainly value in that information, especially when coming from a clinical trials expert with extensive experience, the information is still a snapshot. It is one data point and, as Sanders likes to point out, scientists and statisticians never rely on one data point.

"I think this is true throughout the industry," she says. "We have all of this learned information, but it is dispersed throughout the company, and it is not in a format that is analyzable. Additionally, the decisions we make based on this information do not have confidence intervals. One of my most experienced team members might tell me we should be able to recruit a certain study in 24 months. But we have no consistent and quantifiable way of reflecting how sure or confident we are in that prediction, and we are not set up to capture the basis of that prediction for future reference."

Take Individual Experience Out Of The Equation

Roche is a huge organization, and Sanders has a staff of over 2,500 individuals working in clinical operations and conducting clinical trials across 60 countries. The size of the organization complicates the importance of the decisions she often has to make with incomplete information.

"We are making decisions that have a significant impact on both clinical operations and the company as a whole," she says. "When a company commits to planning for a certain number of programs, those timelines are based on information from the clinical operations group. But too often those decisions are not based on information that is easy to analyze or quantify. As someone who is the head of global clinical operations, I can tell you those decisions can make me feel very uncomfortable."

Sanders is quick to point out that the source of the information does not make it wrong or mean the decisions based on it are incorrect. She stresses again that often the information is coming from brilliant people with a lot of experience performing trials. But as someone who has come into her position from a technical and scientific perspective, she felt the company — and the industry — could do better. If a method could be devised that would apply scientific, quantitative, and highly technical scientific methodologies to the decision-making process, those decisions would no longer need to be dependent on the experience of select individuals.

The first thing she wanted to do was look at what information was available to her. She knew she would need to look at solid data to accurately see what was going on, and she also knew that not having access to that data would again make her feel very uncomfortable with the decisions she would be forced to make.

"We looked at our clinical trials systems and other systems that were available to us," she notes. "I don't think clinical operations had been the focus of high-end technologies in the past, and as a result you find many disparate systems that do not link or overlap in any way. I think this situation is common across the industry, and yet companies still need to collect data from these systems. When the information you need resides in two different places, it is not straightforward to get that information in a timely manner and know that it is accurate."

The Search For An Umbrella Solution

To try to simplify the duplicative data that existed, Roche's late-stage clinical operations group, which is headed by Sanders, launched a program titled Trials and Related Information Systems (TARIS) to try to make sense of the linked and related systems. She acknowledges this effort has taken a lot of resources, and it will take some time to realize the full benefits, but feels that it will all be worthwhile if the end result is a single source of reliable, pertinent data that can be accessed and analyzed at different levels.

"One of the goals is to create an information layer that is an umbrella for all of our clinical trials systems," she says. "If someone wants information, they will not have to go to different systems to get it. In my role, I want to know how we are performing relative to our goals. To do that, I should not have to go to different systems and call on five different CROs. I should be able to see that information on this information layer, because all of the data is being fed directly into it. And

when I find the data I want, I also should have a very high level of confidence in it."

Several different vendors that have information layer technologies are currently being evaluated, and Sanders is also looking at leveraging technologies already in place at Roche. A vendor decision is expected to be made by the end of the second quarter of 2016. She notes there are numerous challenges, including the fact that many of these technologies are still relatively new. Another is getting all internal stakeholders on board. She is taking a slow and measured approach to ensure buy-in from all job functions that will be impacted by the changes. In the meantime, data is being broken up into "core data packages" so as to better move them into the new architecture being built. "This has made it easier to get alignment and has enabled us to test structures with smaller amounts of data and then apply the lessons learned as we move on to the next package," she says.

While the new information layer will not eliminate all of the different systems already in place, it will allow the company to share data more easily and seamlessly across systems and analyze that data via reports and dashboards. According to Sanders, the systems are transactional tools; they facilitate the input or extraction of data, but the information layer will hold the information and remain the single source of truth.

The program already seems to be simplifying the jobs of many in her organization. Roche conducts an incredible number of programs collecting large amounts of trial data. The teams should be able to use this data, with matching analytics and benchmark information, to assess how long it will take to complete a study under different assumptions — and to determine if they can do better.

When the fully implemented information layer is in place, teams and senior leaders like Sanders will have the ability to interrogate the data through queries. Examples of these queries include:

- Which countries/sites have the highest likelihood of delivering on their commitments to patient enrollment?
- If Germany drops out of a study, how will it affect our model?
- If we add more sites to a study, what is the likelihood that the timelines will move up by a quarter?
- How is Roche clinical operations performing relative to industry peers?
- Given our potential portfolio two to three years from now, what operational factors should we start preparing to ensure high likelihood of execution success?

"We need this capability to conduct predictive modeling within the system," she adds. "We need to have the ability to put science, analytics, and sophistication into our feasibility and oversight activities, which will improve the quality of the answers we get. We believe this is a big game changer when it comes to performing clinical trials because to get this capability, we had to deal with many systems. When you have multiple systems in place, things can get very complex if you are not able to 'discipline' the systems to match your needs in the simplest possible way."

Does Clinical Trial Intelligence Belong With You Or Your CRO?

With the value of data increasing every day, many pharma companies are faced with a tough decision: Should we have that intelligence in-house or allow it to reside with CRO partners? On this point, Sanders and her leadership team thought long and hard before coming to a decision. Ultimately, Roche will focus on managing its late-stage studies within the company, with few exceptions, and outsourcing only site monitoring. "The goal is to have Roche staff around the world working with our investigators, being local experts in the therapeutic areas, having close oversight of study quality, and having information from these trials in a standard, comprehensive, and accessible format to make better informed decisions and explorations," Sanders explains.

She cites a few considerations for her team's reasoning. "Global CROs are professionals with expertise and proven ability to execute clinical trials and the flexibility to absorb the large shifts in resource demands inherent in Phase 3 programs. There are many instances when leveraging global CROs is the best, or sometimes the only, way to execute trials. The direction we are taking was driven primarily by our desire to have direct site relationships and in-depth understanding of the environment at the country level to inform the design and planning of trial execution, especially in areas new to us. An equally important driver is the need to have a consistent model to enable rapid and easy data capture and access to clinical trial information across the hundreds of studies and sites in a way that is meaningful."

When asked about the concept of Big Pharma buying a large CRO, Sanders notes that although this is an interesting evolution of the pharma-CRO relationship, Roche late-stage clinical operations has not considered this approach.

Sharing Success Stories With Others

Sanders believes there are many things the industry can do better regarding clinical trials, and she thinks getting companies to work together on solutions will speed their development and implementation. For that reason, she heads up external collaboration initiatives for Roche. She also sits on the board of directors at TransCelerate Biopharma Inc. as the vice chair.

"I always have felt that cooperation is key to success in pharma," she states. "There are areas in which we all compete, but there are areas where

we don't and where working together is smarter. We have an internal theme within Roche product development that's called Smarter Together. We want our people to feel that is the best thing for us to do."

Externally, Sanders believes there has been a major shift in thinking across the industry. Roche was one of the first 10 participants in TransCelerate, and when she was first called about participating in it, her response was "Forget it."

"I was certain that nothing was going to come out of it," she now says with a smile. "I was very cynical of the whole effort. I felt there would be a lot of talking back and forth, and it would take five years before anything would be approved. But after attending just one meeting, I realized it would be a serious collaboration. The structure that Dalvir [Dalvir Gill, CEO of TransCelerate] put in place has made it successful. At the industry level, I think we will continue to see this type of cross-company collaboration."

One success story that Sanders proudly states has already come out of TransCelerate is the Site Qualification Training Program. At Roche there are several clinical operations groups, and by design they all operate independently. That means an investigator working with Roche may have to be trained several times. Taking that to an even higher level, staff at a site working with multiple companies may have to go through the same training multiple times. If there were just 15 individuals working at that site needing 30 training instances, it would result in 450 separate qualifications. That can become a huge problem for both the sponsors and the sites.

"What pharma companies are doing via TransCelerate is just a much smarter way for all of us to do business," says Sanders. "Members have agreed to a set of minimum criteria to enable a voluntary mutual recognition process of GCP Training across member companies. This allows clinical trial investigators and other site personnel to complete GCP training, which may be recognized by other TransCelerate member companies, making it unnecessary to train separately for each participating company. That is a huge relief for any investigator site. It is an investigator-centric approach that we feel will greatly ease their lives and help pharma get medicines to patients faster."

Patient-Centricity Roundtable:

Sponsors, Sites, And CROs Must Work Together To Hear The Patient

ED MISETA Chief Editor, Clinical Leader @EdClinical

Patient-centricity continues to be the hot buzzword in clinical trials. With greater patient-to-patient interactions via the internet, social media, and advocacy groups, sponsor attention to the wants and needs of patients has never been greater. But for all of the attention being paid to it, questions still linger over what it really means and what is actually being done.

For this patient-centricity roundtable, I attempted to bring together some of the most innovative and patient-centered minds in the industry to discuss the efforts being made and what CROs can do to assist with the process. Included in this panel discussion are:

Roslyn Schneider
Global Patient Affairs Lead, Pfizer

Christine Pierre
President, Society of Clinical Research Sites (SCRS)

Kathy Vandebelt
Global Head, Clinical Innovation, Eli Lilly and Company

Beverly Harrison
Head, Patient Support, Office of the Chief Medical Officer, Janssen, the pharmaceuticals group at Johnson & Johnson

Tina Shah
Health Services Researcher & Pulmonary/Critical Care Physician, University of Chicago Hospitals

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It appears patient-centricity/patient voice will continue to be a hot topic in 2016 and beyond. Where does your company currently stand in regard to implementing patient-centric practices? Can you share a few success stories?

Roslyn Schneider: The "success story" here at Pfizer is a clear commitment across functions and levels of leadership to advance patient-centricity in a manner that's beneficial to the patient community. There are serious, disciplined, and often complementary efforts under way to embed patient-centered approaches into our plans and operations and to apply the resources we need to implement our thinking. In addition to the formation of the Office of Global Patient Affairs, we've had patient-centered roles and teams focusing on innovation, advocacy, and policy across our organization. There are additional new roles and work streams to build on relationships that support change.

Other examples are seen in the inclusion of a patient expert on Pfizer's external bioethics advisory panel, another on an external review panel that reviews Pfizer's independent grants for learning and change. We have included patients and advocates as members of multidisciplinary advisory boards in several areas of Pfizer and engaged them earlier in the process to better inform decision making.

Kathy Vandebelt: Lilly is focused on making clinical trials an accessible healthcare option for patients and their healthcare providers. Our clinical innovation and clinical development staff continue to learn more from patients about what they need to better participate in clinical research. Put another way, we want to embrace this notion of evolving along the continuum of "to-for-with" as it pertains to our relationship with patients and how we aim to collaborate with them.

In 2016, we are expanding Lilly TrialGuide (www.lillytrialguide.com), an enduring web presence that helps patients find information about clinical research and trials that may be appropriate care options for them. We are involving patients in the design of protocols through a collaborative effort with the Lilly clinical research staff, investigators, and study coordinators. We are showing our appreciation for patients who contribute to clinical research and are now providing them with layman summaries of the results at the end of the study. We believe this helps patients understand their contribution.

Beverly Harrison: At Janssen, we thoughtfully and systematically place the patient voice at the core of how we operate by implementing programs that address patients' self-expressed needs. A variety of programs are under way to achieve this, including — amongst other programs — transforming how we evaluate patient requests for compassionate use, enhancing the patient experience in the clinical trial setting, committing to transparency of the resulting data, and creating an internal infrastructure to guide employees in the capture and implementation of the patient voice.

Within the clinical trials realm, an active program we have underway is called "Patient Voice in Trial Design." The ultimate goal of this program is for every Janssen trial we design, the patient voice will be just as loud as the many other voices that we have historically sought to guide design decisions, such as key opinion leader physicians. This program involves gaining real world experience with a variety of methods for seeking, listening to, and incorporating the patient voice into clinical trial design and operational planning. To do this, we are in the process of building a "living" toolkit that we can deliver to the organization to provide the know-how and necessary infrastructure. In parallel, we continue to explore novel methods that can be added to the toolkit and to maintain a repository of patient insights for future reference.

Tina Shah: Patient-centered care is a concept that is becoming increasingly important in our health system, and we are targeting ways to streamline the care we deliver in various settings (e.g., ICU, inpatient, outpatient) to revolve around the patient. One effective area of patient-centered innovation has been with our patients who have Chronic Obstructive Pulmonary Disease (COPD), a disease that causes trouble breathing. COPD is a condition now subject to the Medicare Hospital Readmissions Penalty, which seeks to improve patient-centered care by penalizing hospitals for excess readmissions. Our hospital developed a comprehensive care program led by a nurse practitioner that aligned care and implemented evidence-based practices for COPD patients in the inpatient and postdischarge settings. Two critical components of our patient-centered program are: 1) empowering patients through inhaler and disease education; and 2) ensuring continuity with a follow-up visit with our nurse practitioner within one week and a 24-hour patient access line that is also staffed by the same nurse practitioner. Our preliminary results have demonstrated a significant reduction in all-cause 30-day readmissions. At the same time, our patients tell us they love the teaching and feel more knowledgeable about their disease, but have helped us to uncover areas for improvement, such as ensuring that we schedule appointments that fit with their schedules and that we make sure they have all the needed prescriptions in hand before leaving the hospital.

Are CROs able to play a role in protocol design or bringing patient perspectives to the table?

Harrison: CROs can play a very important role in our quest to obtain patient

> *"CROs can play a very important role in our quest to obtain patient perspective into the design and operational implementation of our trials."*

BEVERLY HARRISON
Janssen

perspective into the design and operational implementation of our trials. We are proponents of "supplier-enabled innovation," where we actively help our key suppliers acclimate their products and services to work in the highly complex world of industry-sponsored trials. CROs can enhance our ability to seek and utilize patient voice to guide clinical development decision making by developing needed infrastructure and services to reach out to the right patients in an efficient manner to obtain actionable insights.

Vandebelt: We haven't relied on CROs much, as we've found success in either working directly with patients or trusted patient-focused organizations/patient communities. In fact, for over a year now, we've been collaborating with patients through our own internal program. The program is a collaborative framework that allows us to incorporate investigator and patient input into our study designs, enabling us to work in partnership with patients around the globe.

Schneider: While I can't comment on specific examples, the way CROs help Pfizer incorporate the patient voice is by executing clinical development plans that are more consistently incorporating the patient voice.

Christine Pierre: I agree that it often comes down to clinical plans. Patients can be accessed through the relationship CROs have with sites. CROs that foster partnerships with sites, as opposed to simply performing transaction-based activities, have the opportunity to leverage that site relationship to better understand the site's perspective. This will lead to greater opportunities to provide value to sponsors.

The old model of patient recruitment had pharma going to a CRO, the CRO engaging with sites, and the sites and investigators recruiting patients. How much has that model changed with the advent of social media and patient advocacy groups?

Pierre: Thus far, most sites are reporting that social media has not had a meaningful impact on patient recruitment. Part of the reason for that is sites generally do not actively engage with patient advocacy groups. However, when the sponsor or CRO works to make that connection, the results can and have been very powerful. Patient advocacy groups are in the business of actively ensuring the patient's voice is being heard, and they can provide a unique and meaningful dialogue with the research community.

Shah: That model still seems to be the predominant method of patient recruitment in the U.S., but social media is complementary and is a relatively untapped arena. Social media allows for a greater audience and also personal experiences from patient to patient that can increase the interest and credibility of studies from the patient perspective. Pairing with patient advocacy groups on

Twitter, for example, can increase the reach to the particular patient population of interest in a relatively low-cost way. Social media will continue to increase in importance for patient recruitment and is a great tool to get the right patients into the right trial.

Schneider: Christine and Tina both make good points, but from the sponsor perspective, I also see the recruitment model changing to better identify eligible clinical trial participants where they are rather than where we are. Engaging patient advocacy groups early and in a disciplined way is valuable in understanding and overcoming potential barriers to patient recruitment and retention. Strategies may extend beyond the "traditional" to utilize the work of patient advocacy groups, social media, community leaders, and others.

> *"Thus far, most sites are reporting that social media has not had a meaningful impact on patient recruitment."*
>
> **CHRISTINE PIERRE**
> Society of Clinical Research Sites (SCRS)

Vandebelt: Those are great comments. I would just add that for many conditions, sites and investigators will typically recruit patients who are already known to them. Through the use of advertising and other relevant content, new patients unknown to the site may also become aware of the study.

The internet provides the opportunity for many more patients to become aware of clinical research as a care option. Research has shown that 42 percent of the world's population uses the internet, the average internet user spends two hours on the web via their mobile device, and 62 percent of smartphone owners used their phone to look up a healthcare condition within the last year. This is a trend we cannot ignore. Through the internet and social media, patients also have the opportunity to share their clinical research experiences with others, including a large number of potential patients. This is an opportunity for many more patients, previously unknown to the sites and investigators, to be informed about a clinical trial and potentially seek additional information about participating.

Harrison: The prevalence of organized patient groups has played a major role in shaping the recruitment process. Patients increasingly look to their peers for advice on care options, and peer guidance can be a big influencer of patients' decisions to participate in trials. It's normal now for the patients to be the ones approaching researchers — both sites and industry sponsors — versus the other way around.

We have a great example from a project we did in 2013 of how a digital patient community, operated by a major CRO, enabled recruitment for a research study. We ran an entirely "direct to patient" noninterventional study, whereby patients who were part of the CROs-owned patient registry were invited to join a study that required submission of health records and a specimen for genetic testing to 23andMe. In just 18 weeks, 1,000 patients were recruited, data provision rates were very high, and the cost of conducting this study was 50 times lower than if we had used a traditional site-centric model.

We often talk about how we need to give the patient a seat at the table during the trial design process. Is it important to also have the CRO, the investigator, or someone from the clinical site seated at that same table?

Harrison: It is very important to have all stakeholders at the table and giving input into clinical trial design. Each has its own unique perspective, and that is vital to designing R&D programs that work — both scientifically and operationally — and ensuring relevant products that deliver value for patients emerge at the end. What one stakeholder can learn from the other in the process is equally important and can help shape and improve the individual role they play. Forums enabled by technology can greatly help to bring all these parties to the same table when it's not logistically possible to literally do so.

Schneider: It's absolutely essential, especially at Pfizer where we rely on successful partnerships with leading CROs. We have CRO partners who are asking for seats at the table when we are engaging patients for insight, and we encourage them to participate. There are several "tables" where we are convening with stakeholders, including in the clinic where the patients, coordinators, investigators, and others may be brought together to simulate clinical trial protocols in a clinical setting.

Pierre: Thank you, Roslyn. As someone who represents the sites, I am incredibly encouraged when I hear comments like that. When you think about it, sites are really an extension of the patients in many ways. The sites are the only part

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of the research study team that have the privilege of actively engaging with the patient. Most sites typically conduct multiple studies and, therefore, have a unique vantage point of seeing which study designs actually work and what challenges are faced by others. At SCRS, one of our goals is to provide the site's perspective to many forward-thinking sponsors and CROs to ensure the voices of the site and the patient are being incorporated into the trial design process.

Shah: I completely agree — this is very important. That qualitative piece of information, the patient voice, allows investigators to quickly know what will and won't work in practice. In order to maximize enrollment and reduce attrition, getting the perspective of all stakeholders right up front would be very helpful.

The recruitment rate for trials is still very low, and a recent report stated that 85 percent of cancer patients are still not aware that clinical trials are a treatment option. What can sponsors, CROs, sites, and investigators collectively do to make patients more aware of trials and get greater involvement in them?

Shah: Great question. Getting the message about available trials to patients can be tough due to the wide variation in patient use of social media, as well as patient understanding of their medical disease and what a clinical trial offers and entails. A two-pronged approach at the level of the bedside and through the internet will allow us to reach more patients.

Making providers aware of relevant clinical trials for their patients is key. This should be done in a time-efficient manner with feedback and updates to providers that refer patients for trial screening. Providers should also be armed with an easy way to connect their patients to sites, investigators, and CROs, whether it is via handouts or an email that can be forwarded to their patients. On the media end, a patient-friendly website that details available trials with links to disease websites often frequented by savvy patients would also help increase knowledge of studies and enrollment. The website should be updated frequently so the information does not become stale. Partnering with disease-based organizations that have already built patient networks can further leverage the effort to inform patients of the benefits of trials.

Vandebelt: Despite the low enrollment rates, many patients who participate in a clinical trial report having a positive experience. Ironically, a majority of patients don't actively discuss their trial experience. Why is that? If there are ways we can enable patients to have more meaningful conversations with their loved ones, caregivers, social networks, and physicians, then maybe we can move the needle on raising awareness. That is one of the reasons Lilly is exploring ways to appropriately provide patients with overall trial results or even their own clinical data to enable meaningful conversations about their participation in a way that is respectful, ethical, and informative.

Schneider: There are many reasons why people may not consider a clinical trial as an option, including but not limited to the lack of awareness or preconceived notions of what the clinical trial experience might be like. These are issues in both the patient and the healthcare provider communities. Improving awareness of clinical trials in patient communities may be done through advocacy groups, local community, media, and social and other channels. Primary care, specialty healthcare providers, and health systems may be engaged in a more holistic, coordinated fashion to help identify the most appropriate patients for specific trials. This approach helps ensure that patients and their healthcare teams are better prepared to consider a clinical trial as an option.

Harrison: "Collectively" is the key word here. No one party can address this problem on its own; we all have to work together collaboratively. Patients themselves can help too, to spread the word to their peers, and industry, sites, and CROs can help enable this. Within Janssen, we are currently investing in a comprehensive program that will greatly enhance the accessibility of information about our sponsored trials and expect the program to go live by the end of the year. Janssen also participates actively in TransCelerate, CTTI (Clinical Trials Transformation Initiative), and other multistakeholder and industrywide forums that seek collaborative solutions to the problem of low trial participation rates.

Pierre: I agree that "collectively" is the key word. For years we have conducted surveys and attempted to document the reasons why the general public does not participate in clinical trials. It is now incumbent upon us as a collective industry to tackle these very difficult and far-reaching issues. Awareness, knowledge, and accessibility all need to be addressed with the general public to change the perception of trials and the entire industry. Lastly, respect for the patients who do participate needs to be acknowledged. Study results and the patient's own clinical data should be returned to them at the appropriate time to recognize and thank them for their critical and unselfish contribution. Those contributions to the general body of scientific knowledge are what will allow us to continue to bring new treatments to patients.

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What Will The CRO Of The Future Look Like?

ED MISETA Chief Editor, Clinical Leader @EdClinical

The world of clinical trials is changing. New technologies are changing how trials are performed. The internet and social media have enabled greater patient connections, which will continue to change how patients are recruited. And Big Data, genomics, biosimilars, and precision medicine will change the industry in still unknown ways.

With all of the clinical work being outsourced, there is no question these changes will affect CROs as well. In fact, it makes you wonder what exactly the CRO of the future will look like.

"Our world has changed, and our way of getting the work done has changed. CROs started off as companies providing services for pharma companies in areas where they did not have a lot of volume. But since then they have transitioned more to providing services in niche areas, such as biostatistics, preclinical toxicity development, and assay testing. When these companies started spreading across the world, greater collaboration with Big Pharma companies came with that expansion. Nowadays they can even help companies to commercialize their products. We have gotten to the point where there is almost nothing they can't do."

ANDREW LEE
SVP, head of global clinical trial operations at Merck, speaking at Disruptive Innovations 2015

When major consulting firms started advising pharma companies to focus on their core competencies, that led many to strip down to just R&D, which consequently created the current trend toward strategic partnerships. Those partnerships have obviously pushed millions of dollars into the CRO space and made sponsors more dependent on CRO services.

But can all of this growth in the CRO industry continue? The largest growth right now seems to be in the biotech space, but the main factor poised to drive CRO growth in the future is whether or not service providers can adapt to pharma needs in the future. In fact, this concept of identifying and providing services for the future needs of the biopharma industry is exactly what will keep the CRO industry growing.

Solomon Babani, global VP, alliance management for Covance, believes there are hurdles CROs will need to overcome. In talking to biotech firms, he has found many of them do not believe the larger CROs have what it takes (or really care) to engage profitably with smaller companies. He now spends a lot of his time educating these companies not only on what they should be asking for, but how to ask for it.

"CROs have the capability to put fundamentally different types of teams in place; they just need to understand the needs of their clients," he says. "We can customize a program to meet their development needs as long as companies are able to articulate what they need. The ability to put these teams in place has been enhanced by the ability of CROs to attract top talent. Now that CROs have that expertise, they are better able to design development programs for companies of any size."

SOLOMON BABANI
global VP, alliance management for Covance

IS TRUE STANDARDIZATION JUST A DREAM?

Paul Colvin, EVP, global clinical development for PPD, believes the time to change is now because the industry continues to see increased complexity, rising costs, and greater pricing pressures. According to Colvin, CROs and pharma must find ways of partnering to bend the cost and time curve.

"Competition in our business is normal and healthy. However, we should not compete around things like standardization of metrics and definitions, because that only drives inefficiency, duplication, miscommunication, and significant costs. The real competition should be around the best molecules, the strongest talent, and the creation of a system-agnostic development process that supports the seamless integration of best-in-class technology and disruptive innovations. But CROs cannot do it alone. It must be a collaborative effort across the entire drug development industry. It is our joint mission to improve the health of patients and lower the cost of development"

PAUL COLVIN
EVP, global clinical development for PPD

Colvin would like to see a level of standardization throughout the industry that would allow everyone to use the same set of metrics and definitions, which he says will allow for faster and better data integration and will set a clear baseline across all trials for improved predictive analytics. But is it possible to accomplish that true standardization?

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more difficult today, he noted, because of the need to map all the different standards and definitions among systems. Doing so is extremely labor-intensive and weakens the overall quality of the analysis. At the same time, access to the plethora of data sources, such as from health networks, insurance payers, pharmacies, and patients, makes it ever more critical to have standards in place. And that standardization must include how to collect and integrate patient data.

While technology, standardization, and talent are key factors, Colvin says we must remain focused on the patient. He believes using a more patient-centric model will help to better engage and encourage patient participation in trials because of the greater convenience it will offer. "As an industry, we need to place even more emphasis on the patient, and as new technology and innovations are developed, we need to use them to improve the patient experience and their level of engagement," he noted. Colvin feels significant progress can be made in that respect via such tools as mobile health, telemedicine, minute clinics, and patient concierges — all of which are helping to make it easier for patients and volunteers to participate in clinical trials and increasing the efficiency and effectiveness of conducting those trials.

Jamie Macdonald, CEO of INC Research, agrees standardization is important. He notes the CRO Forum is already in the process of collaborating with TransCelerate on several of their initiatives, in addition to working with other industry groups.

"TransCelerate is one part of this industry, but there are others. We will need to include and get the support of all of these groups, and we are making the linkages. If a common technology is going to be made available, and people are open to sharing it, then that certainly bodes well for the industry."

JAMIE MACDONALD
CEO of INC Research

Still, Macdonald adds the real challenge for the industry is that, even with the best research and molecules, you still need to have motivated investigators with access to qualified patients. As we continue to move toward targeted medicines, the old paradigms of site identification and patient recruitment will not get sponsor companies the enrollment numbers needed in the necessary time frame to make trials more timely and efficient.

UNDERSTAND OUR CHALLENGES

So what are the critical challenges CROs face that they would like sponsor companies to better understand? The first would be for pharma to develop better relationships with the entire healthcare community. Or stated differently, how can we make clinical trials an option for all eligible patients? We all know it does not happen often enough. Data shows only 3 percent of physicians in the U.S. have ever been principal investigators, and half of those no longer work in research. "As a result, we are dealing with a very small pool of investigators," says Macdonald. "The industry needs to stop its practice of rejecting investigators who have received a 483 without even knowing the reason for the warning. If a sponsor changes a protocol seven times, they shouldn't be surprised if there is a protocol deviation. We need to do more to help these physicians succeed."

Finding eligible patients who are comfortable participating in research and can adhere to the requirements of a protocol is also essential. A unified patient registry for each disease that can be shared by companies might be a step in the right direction. Changing patient perceptions of the industry is also critical. It should come as no surprise to anyone reading this article that the reputation of the pharma industry can oftentimes not be conducive to patients volunteering to participate in a trial.

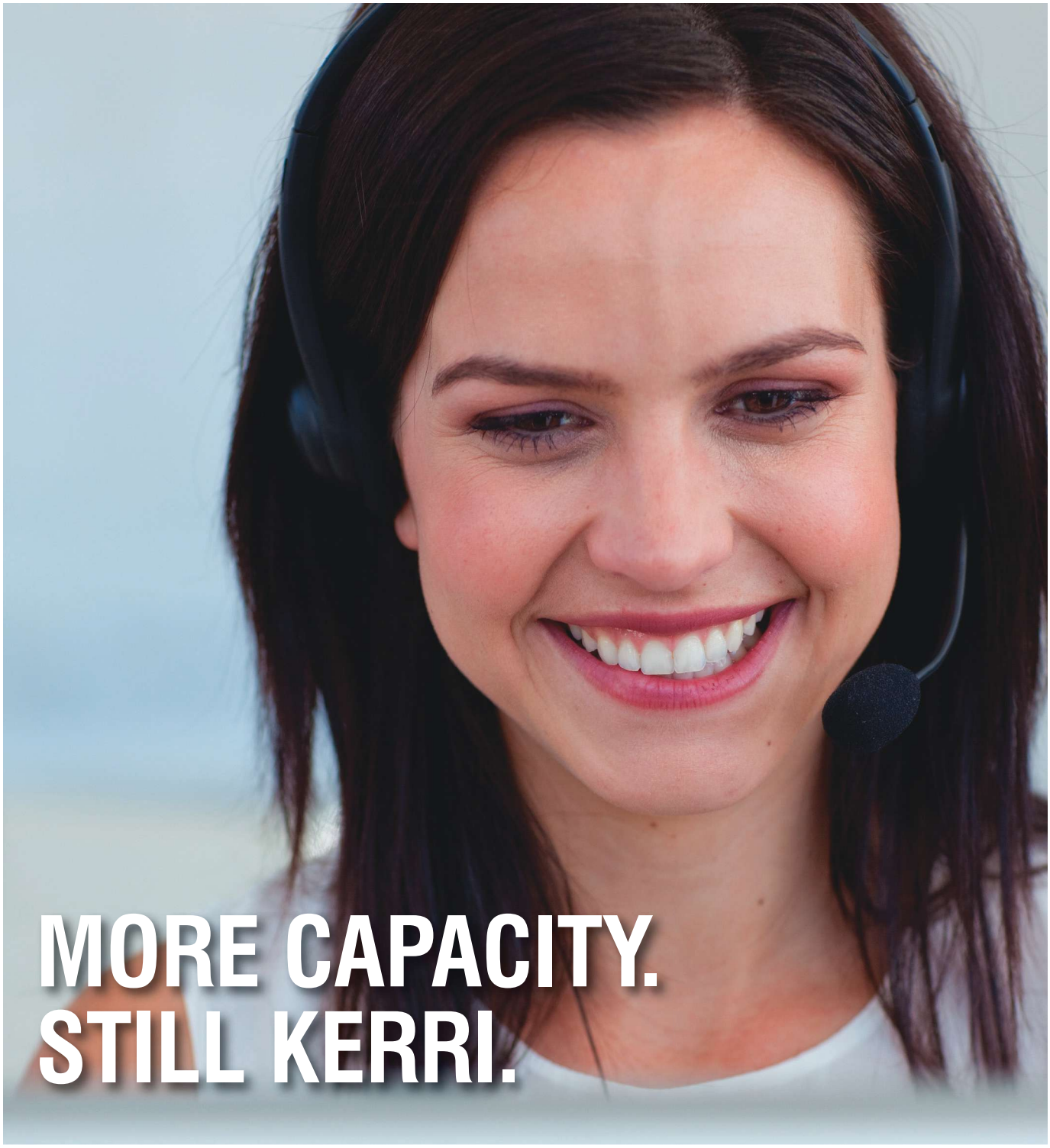
Of course, the day will also come when sponsor companies become much more adept at collecting data, moving it around, and engaging potential patients. When that happens, will we eventually see a time when pharma discovers a new molecule and opts to work with Google or Apple, forgoing CROs altogether?

While Macdonald acknowledges that could very well be a reality in the future, he does not believe it will happen. "Innovation breeds more innovation," he says. "IBM's Watson is already working in the clinical space helping to identify patients. But the industry is still in need of an honest broker that will match a patient with the right physician and the right protocol. That will likely not be a sponsor company because they have too much of a vested interest. But I think it will happen with CROs or some other agents in that process."

CROs partnering with labs that are more centrally located to patients is one example of how they can better assist pharma in connecting with patients. Babani notes when Covance and Lab Corp combined their companies in 2015, Covance gained access to a wealth of patient information. However, he says companies need to move forward with caution, since those patients will need to give permission for their samples to be used in clinical development. Still, the concept of allowing patients to visit local labs as opposed to traveling to physicians' offices will be a win. In any trial, patients need to give blood, and CROs should do everything they can to make that process as easy as possible. It is also another way for CROs to distinguish themselves in the future.

Finally, having a CRO that can "think on its feet" and make the right decision when situations arise may also be a sought-after commodity. As a result, the days of the project manager at a CRO calling a sponsor to ask how a problem should be resolved may be a thing of the past. This is especially true as CROs continue to hire more personnel with experience in pharma and bio or who have a track record of having supported those companies.

While it might be hard to predict what the typical CRO will look like in five to 10 years, I don't think the concept of CROs will go away anytime soon. But that doesn't mean the role of the CRO can't continue to change and evolve. Those that do the best job of meeting the needs of pharma companies, and even anticipating those needs before they arise, will be successful. They will also build confidence in the companies with which they hope to do business. Those partners that cease to bring value to sponsors or do not provide any more value than what the sponsors themselves bring will be the ones most likely to struggle.



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Operationalizing Collaboration: How Sponsor-CRO Disconnects Hold Back Clinical Trial Quality

LAKSHMI SUNDAR VP strategy and development, The Avoca Group

In recent years, the pharmaceutical industry has been pulled in opposite directions by the historic approaches that have served it well in the past and the new thinking many claim it must adopt to thrive going forward. Advocates of the new approach argue pharma must "bust silos" and forge ever-closer ties with CROs and even rivals. Research conducted by The Avoca Group reveals clear boundaryless communication is a crucial aspect of driving quality in clinical trials. With some silos essential to pharma and an industry built on protecting intellectual property, can we perform precision silo-busting?

The argument in favor of eliminating the barriers both within and between organizations is now well into its third decade. Since 1990 when GE first envisioned building "a boundaryless company ... where we knock down the walls that separate us from each other on the inside and from our key constituencies on the outside," many an article has espoused the monetary and nonmonetary value of breaking down silos for better collaboration. Yet businesses in multiple industries are still trying, with varying degrees of success, to achieve this goal.

Part of the difficulty stems from the fact that rigid, demarcated structures can be advantageous. When such structures are in place, roles and reporting lines, which are valuable at large organizations, are clear and easily understood. The sprawling global operations of the leading pharma companies and CROs make them prime candidates to benefit from internal silos. As well as contending with these pan-industry issues, large pharma companies face a set of challenges specific to drug development. Collaboration is difficult, yet survey data suggests it is something the industry must embrace if it is to eliminate current inefficiencies.

DEMONSTRATING THE SPONSOR-CRO DISCONNECT

The results of a 2015 Avoca survey of 226 people from sponsors and 202 from CROs illustrate the shortcomings of the current situation. While many sponsors have tried to form closer ties to a small pool of outsourcing partners in recent years, the survey suggests the relationships are yet to mature into the seamless collaborative alliances GE envisioned in 1990.

"[Sponsors don't give us] ownership of decisions that we should have. This delays our deliverables which sponsors will hold us accountable for in the end." **[CRO]**

"CROs don't like to problem solve and offer suggestions. They'd rather just do as they are told." **[Sponsor]**

"One sponsor that I work with is new to fully outsourced trials, so at the beginning of our working relationship, they micromanaged us." **[CRO]**

Such struggles are evident in sponsor and CRO perceptions of their own and each other's attempts to create integrated quality management systems (QMS). There is widespread acceptance that an integrated QMS, in which all of the processes and tools work together to ensure clinical trial quality, is of value. Yet when Avoca asked sponsors and CROs about the extent to which they and their partners have integrated QMS, neither group came close to strongly agreeing that such systems are in place.

The shortcomings of existing attempts at integrated QMS were one of the few areas of agreement between CROs and sponsors. CROs consistently rated all other aspects of their own QMS highly. Yet when sponsors were asked to rate their CROs' QMS, they gave middling scores across the board. The disconnect in perceptions suggests there is a breakdown in communication. If the QMS are as good as CROs think they are, the benefits are not being made clear to sponsors. If the QMS are as flawed as sponsors think they are, the shortcomings are not being conveyed clearly to CROs.

There is clear evidence that high levels of sponsor satisfaction are highly correlated to clear articulation of roles and responsibilities in forging strategic relationships between sponsor and CRO.

LEARNING FROM OTHER INDUSTRIES

In trying to successfully operationalize collaboration, sponsors and CROs can learn from experiments run by their peers and companies grappling with similar problems in other industries. Younger companies, uninhibited by the institutionalized thinking that can take hold over decades, are trying some of the bolder ideas. Facebook, for example, puts each new hire through a six-week boot camp before they join their specialized teams so as to form bonds between people in different parts of the company.

If sponsor and CRO staff went through intercompany bootcamps, would they retain the divergent perceptions that are evident in the survey data? Or would their shared backgrounds lead to a more coherent vision of the state of clinical trials and how they can be improved? Given the specialized skills and intercompany

collaboration that characterize clinical research, it may be impossible to copy the Facebook approach directly, but our industry can try — and, in some cases, is trying — to implement methods that share its intentions.

At Avoca, we have seen some of the companies we work with apply innovative approaches to breaking down barriers and facilitating better collaboration. Clear discussions centered on partnering for risk mitigation appear to open up new lines of dialogue and innovative approaches.

The endeavor to facilitate collaboration by altering the mindsets of workers has parallels in other parts of the healthcare system. In a hospital, doctors are typically segregated as they were in medical school, putting physicians and surgeons on opposite sides. Yet when a patient goes to a hospital, they just want the most appropriate, skilled group of people to work collectively to treat their condition. Recognizing this, the Cleveland Clinic reorganized its teams around how patients interact with the hospital, and their organization rose to the top of patient satisfaction tables.

In clinical research, the need for intercompany collaboration adds an extra layer of complexity, but sponsors and CROs, like the Cleveland Clinic, are still trying to instill mindsets that facilitate the operationalization of collaboration. The aforementioned joint team is one way to try to achieve this goal. Another is being pursued by a large CRO. The firm has set up a team dedicated to running big trials for small biotechs, a group that can get overlooked by CROs. While Big Pharma companies account for most of the CRO's sales, the biotech-focused team's success is tied to different metrics.

The team's overarching task is to understand and meet the needs of biotechs. By learning to think like a biotech, the team may be able to resolve some of the disconnected perceptions evident in the survey data. Ironically, the CRO is driving toward this goal by siloing off the team from the rest of the company, which only serves to reiterate the complexity of operationalizing collaboration.

RUNNING EXPERIMENTS TO OPERATIONALIZE COLLABORATION

The experience of the large CRO illustrates the naïveté of the gung-ho calls for silo-busting. In a field as complex, multifaceted, and reliant on intellectual property as clinical research, some barriers are needed. The challenge for sponsors and CROs is to know which business structures are essential and which are burdens.

Lessons learnt from experiments now under way at sponsors and CROs will shape the path forward, as will analyses of what is working in other industries. Yet the slow progress seen in survey data from the past few years shows we must continue to propose and test hypotheses. If we are to create highly functional and integrated clinical operations that are based on sharing of information between functions and partners, we will need to try and test new ideas. Applying technological Band-Aids to a system that needs surgery will deprive us of true collaboration and insight.

Use Peers' Experiences To Make Educated CRO Selections

REBECCA MCAVOY Market Research Director, Industry Standard Research

Life Science Leader *(LSL) and Industry Standard Research (ISR) have recently partnered to bring readers a robust methodology for evaluating and selecting CROs. ISR collects and analyzes data from users with hands-on experience working with service providers within the past 18 months to provide LSL and the pharmaceutical industry with detailed insights into CRO performance. LSL uses this data to identify service providers that have earned leadership positions and award them in various categories of service.*

"Users with hands-on experience" is an important phrase to note in the above paragraph. Imagine a scenario in which you need to choose a restaurant to host an important event but you've never personally eaten at any of the restaurants on your short list. Gathering opinions on the restaurant from prior patrons who have sampled the fare and experienced the service and ambiance would provide an excellent proxy for the experience of actually dining in the restaurant. Fortunately for those choosing a restaurant, websites with user reviews allow this information to be at your fingertips within moments. In the pharmaceutical outsourcing industry, information from users takes substantially more effort to come by – but the knowledge gained is well worth the effort.

Utilizing information from recent users of CROs is the same idea as utilizing user reviews to make a more educated product purchase or select an appropriate restaurant for your needs. However, the data ISR has collected about CROs' performance is much more structured and detailed than the wide-ranging open-end responses found on most user review websites. Recent users of CROs provide ratings along 25+ performance attributes across a variety of categories. They are also asked to rate their satisfaction with each provider they've used, the likelihood that they would use the provider again, and the likelihood that they would recommend that provider to a colleague. Furthermore, respondents are asked to explain their satisfaction ratings in an open-ended fashion, enabling the reader to understand details regarding how the service provider's performance may have impressed a given user or what a particular pain point may have been. This approach provides a comprehensive look into what it would be like to work with a provider for an outsourced clinical development project.

Having access to performance data from CROs' users is crucial in making an informed CRO selection. However, it is a lot of information to process, and it is helpful to have a plan for evaluating this information. To further aid in the process of choosing a CRO, ISR collected information regarding the criteria considered most important to industry decision-makers when selecting a provider for their outsourced work. CRO selection decisions are not made in a vacuum. They're most often made by a team of people with a variety of factors to consider. Additionally, many decision-making units have company guidelines to which they must adhere.

Not all selection environments are equal. The same rules and preferences may not necessarily apply as the selection environment differs. Selecting among preferred providers, selecting a provider that is not on the company's

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preferred list, and selecting a provider when a preferred list does not exist may lead to different priorities and interests taking precedence in the decision. To investigate this further, ISR asked respondents with Phase 2/3 decision-making responsibilities about selection criteria when choosing providers in each of the aforementioned selection environments. Figure 1 displays the five most important attributes in each of the decision-making scenarios and illustrates how each scenario can allow selection attributes to become more or less relevant.

Operational excellence and therapeutic expertise rank among the top-five most important selection drivers in each decision-making environment. In fact, *operational excellence* is the #1 most important attribute in each of the environments. Not surprisingly, these areas are critical for selection regardless of how a provider is chosen.

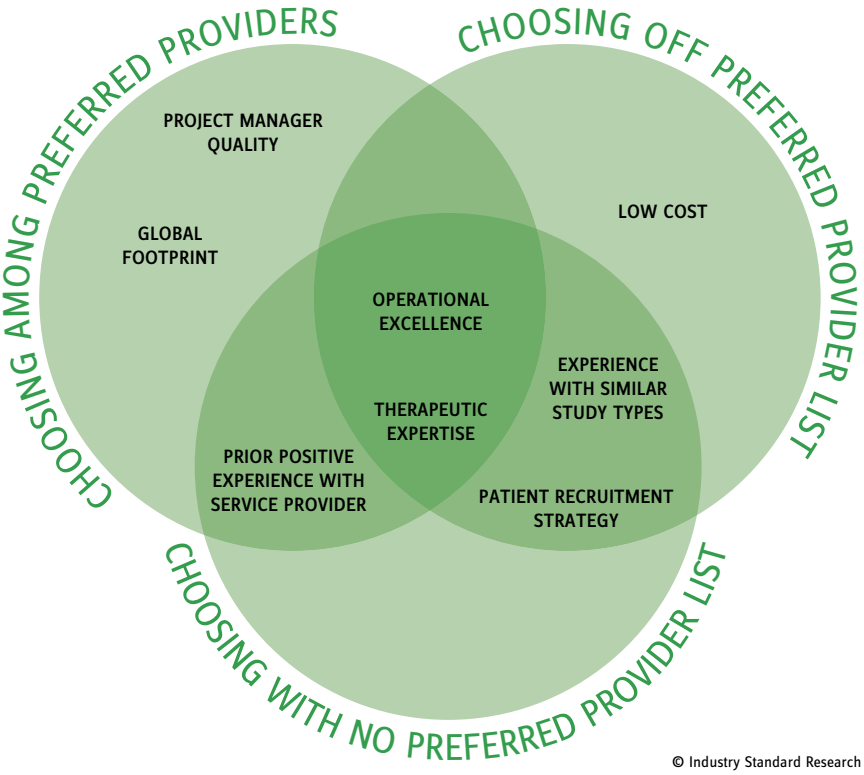
Now to examine the nuances of each of the scenarios: When choosing among preferred providers, project manager quality and global footprint are among the top-five most important attributes, but this is not the case for the other scenarios. A decision-making scenario could easily be imagined where stakeholders know that the providers have the necessary operational and therapeutic experience (due to the vetting process they underwent to be included on the preferred list) and now need to further narrow the list of potential providers based on whether the project managers are of sufficient caliber and whether the geographic scope can be managed successfully.

Choosing a provider that is not on the company's preferred list and choosing a provider in absence of a preferred list yield similar results in terms of the most important attributes. Decision-makers are looking for providers to have *experience with similar study types* and for strong *patient recruitment strategy*. Desiring experience with similar study types is logical, since the providers have not already been through a preferred provider vetting process to ensure that they have sufficient experience.

Low cost also comes into play when choosing a provider not on the company's preferred list. As preferred provider agreements often include pre-negotiated rates, decision-makers may be more price-sensitive when choosing a provider with which they do not already have an agreement.

CRO performance ratings and an understanding of CRO selection criteria are essential tools in an organization's choice of service providers. Decision-makers at sponsor companies can use the experiences and insights of their peers as a lens through which to examine and enhance their own approaches to clinical outsourcing. For CROs, knowing where their business exceeds expectations and where it falls short will aid in marketing their abilities and improving potential shortcomings.

Figure 1



Survey Methodology: Industry Standard Research is a full-service market research provider to the pharma and pharma services industries. ISR's CRO quality benchmarking research is conducted annually via an online survey. For the 2016 CRO Awards data, more than 60 service providers were evaluated on over 25 different performance metrics. Research participants were recruited from biopharmaceutical companies of all sizes and screened for decision-making influence and authority when it comes to working with CROs. Respondents only evaluate 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.

For more information, please visit www.ISRreports.com.

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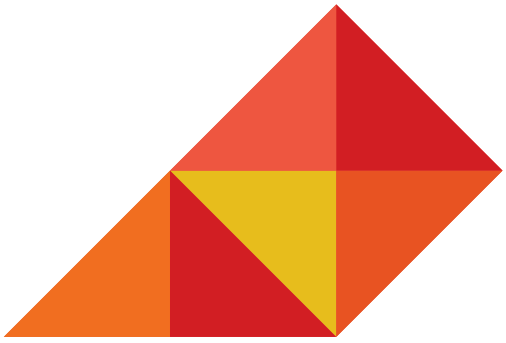

CRO LEADERSHIP AWARDS 2016

Life Science Leader's readership of pharmaceutical and biopharmaceutical executives 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.

Based on research from Industry Standard Research's Contract Research Organization Quality Benchmarking annual online survey, 65 contract research organizations 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 only evaluate 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

CRO LEADERSHIP AWARDS 2016 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

CHDR
CRS Clinical Research Services Andernach GmbH
Vince & Associates Clinical Research
BIOTRIAL

BIG PHARMA

CRS Clinical Research Services Andernach GmbH
Eurofins

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

Eurofins
US Oncology
SGS Life Science Services
Tata
Eurotrials
Covance
Inamed
Quintiles
Quotient Clinical
Worldwide Clinical Trials
PPD
Pharm-Olam International
DaVita Clinical Research
Celerion
Accelovance
PAREXEL
Chiltern

BIG PHARMA

SGS Life Science Services
WCCT Global
Tata
Quotient Clinical
Covance
Worldwide Clinical Trials
PRA
PPD
INC Research
Quintiles
Premier Research
PAREXEL
SynteractHCR
Medpace
TKL Research
NAMSA
Celerion

SMALL PHARMA

Eurotrials
CRS Clinical Research Services Andernach GmbH
Eurofins
Novotech
Vince & Associates Clinical Research
DaVita Clinical Research
Pharm-Olam International
Duke Clinical Research Institute
Quintiles
Chiltern
Lambda Therapeutic Research
Celerion
BioClinica

MET CUSTOMER EXPECTATIONS

OVERALL

WCCT Global
Lambda Therapeutic Research
Medpace
Bioskin
PRA
TKL Research
INC Research
ICON
Novotech
NAMSA

BIG PHARMA

DaVita Clinical Research
ICON
QPS Holdings
Eurotrials

SMALL PHARMA

PAREXEL
Covance
Algorithme Pharma
Medpace
Rho
PPD

CRO LEADERSHIP AWARDS 2016
COMPATIBILITY

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

COMPATIBILITY

TOP PERFORMERS

OVERALL
BIOTRIAL
Pharm-Olam International

BIG PHARMA
SGS Life Science Services
CRS Clinical Research Services Andernach GmbH

SMALL PHARMA
Pharm-Olam International

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL
SGS Life Science Services
CRS Clinical Research Services Andernach GmbH
Tata
Vince & Associates Clinical Research
Eurofins
Worldwide Clinical Trials
Chiltern
CHDR
Medpace
SynteractHCR
Quotient Clinical
QPS Holdings
Lambda Therapeutic Research
PPD
Covance
DaVita Clinical Research
Rho
INC Research
Inamed
Novotech

BIG PHARMA
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Tata
SynteractHCR
Quotient Clinical
INC Research
WCCT Global
PRA
PPD
Eurofins
Medpace
Covance
QPS Holdings
DaVita Clinical Research
Premier Research
NAMSA
inVentiv Health
Chiltern

SMALL PHARMA
Eurofins
Chiltern
Lambda Therapeutic Research
Vince & Associates Clinical Research
Rho
Eurotrials
Medpace
QPS Holdings
Novotech
CRS Clinical Research Services Andernach GmbH
TKL Research
Worldwide Clinical Trials
DaVita Clinical Research

MET CUSTOMER EXPECTATIONS

OVERALL
PRA
US Oncology
Medsource
PAREXEL
Quintiles
ICON
NAMSA
WCCT Global
TKL Research
inVentiv Health

BIG PHARMA
Quintiles
ICON
PAREXEL
Celerion
Rho

SMALL PHARMA
SGS Life Science Services
PPD
SynteractHCR
Quotient Clinical
BioClinica
Covance
PAREXEL
Quintiles
Duke Clinical Research Institute

CRO LEADERSHIP AWARDS 2016 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

CHDR
BIOTRIAL

BIG PHARMA

Quotient Clinical
SGS Life Science Services

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

US Oncology
CRS Clinical Research Services Andernach GmbH
SGS Life Science Services
Eurofins
Vince & Associates Clinical Research
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Quotient Clinical
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Eurotrials
PPD
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Quintiles
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Algorithme Pharma
QPS Holdings
Tata
Medpace
Inamed
Chiltern
Duke Clinical Research Institute
WCCT Global
PRA
Lambda Therapeutic Research
NAMSA
INC Research
Celerion
PAREXEL

BIG PHARMA

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Worldwide Clinical Trials
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PRA
PPD
Covance
QPS Holdings
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Quintiles
Celerion
Premier Research
DaVita Clinical Research
Tata
SynteractHCR
NAMSA
Eurotrials

SMALL PHARMA

Duke Clinical Research Institute
Pharm-Olam International
Eurotrials
Eurofins
CRS Clinical Research Services Andernach GmbH
Lambda Therapeutic Research
Medpace
Chiltern
DaVita Clinical Research
Algorithme Pharma
Quintiles
SGS Life Science Services
Vince & Associates Clinical Research
PAREXEL
Covance
Novotech
TKL Research
PPD
Worldwide Clinical Trials
BioClinica
QPS Holdings

MET CUSTOMER EXPECTATIONS

OVERALL

TKL Research
Rho
Bioskin

BIG PHARMA

Duke Clinical Research Institute
Medpace
inVentiv Health
PAREXEL
TKL Research
Chiltern
ICON

SMALL PHARMA

Rho
Quotient Clinical

CRO LEADERSHIP AWARDS 2016 QUALITY

- Data quality
- Project manager quality
- CRA quality

QUALITY

TOP PERFORMERS

OVERALL

BIOTRIAL
CHDR
SGS Life Science Services

BIG PHARMA

WCCT Global
SGS Life Science Services
Quotient Clinical
Worldwide Clinical Trials

SMALL PHARMA

Novotech
Eurotrials

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

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Lambda Therapeutic Research
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Quintiles
Chiltern
INC Research
WCCT Global
Eurotrials

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Tata
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INC Research
DaVita Clinical Research
QPS Holdings
Medpace
Quintiles
Premier Research
Rho
inVentiv Health

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DaVita Clinical Research
Medpace
Rho
Duke Clinical Research Institute
Eurofins
Chiltern
TKL Research
Pharm-Olam International
Worldwide Clinical Trials
Covance

MET CUSTOMER EXPECTATIONS

OVERALL

TKL Research
SynteractHCR
PRA
PAREXEL
Duke Clinical Research Institute
ICON
Bioskin
Celerion
BioClinica

BIG PHARMA

ICON
Celerion
PAREXEL

SMALL PHARMA

QPS Holdings
SGS Life Science Services
Quintiles
PAREXEL
BioClinica
INC Research
Celerion

CRO LEADERSHIP AWARDS 2016 RELIABILITY

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

RELIABILITY

TOP PERFORMERS

OVERALL

BIOTRIAL
CRS Clinical Research Services Andernach GmbH

BIG PHARMA

CRS Clinical Research Services Andernach GmbH
Worldwide Clinical Trials
WCCT Global

SMALL PHARMA

Eurotrials

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

Worldwide Clinical Trials
Eurofins
CHDR
SGS Life Science Services
US Oncology
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Medpace
DaVita Clinical Research
Quotient Clinical
Eurotrials
Tata
Algorithme Pharma
Novotech
Lambda Therapeutic Research
WCCT Global
Covance
Vince & Associates Clinical Research
PPD

BIG PHARMA

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Eurofins
Quotient Clinical
DaVita Clinical Research
INC Research
QPS Holdings
PRA
Covance
Tata
PPD
Medpace
Premier Research
Quintiles

SMALL PHARMA

Eurofins
Novotech
Medpace
Chiltern
Pharm-Olam International
SGS Life Science Services
Lambda Therapeutic Research
Algorithme Pharma
Rho
CRS Clinical Research Services Andernach GmbH
DaVita Clinical Research

MET CUSTOMER EXPECTATIONS

OVERALL

Rho
QPS Holdings
Quintiles
Inamed
PRA
Medsource
Bioskin

BIG PHARMA

Celerion
PAREXEL
Chiltern
SynteractHCR
inVentiv Health

SMALL PHARMA

Quotient Clinical
BioClinica
Worldwide Clinical Trials
Vince & Associates Clinical Research
Quintiles
TKL Research
Duke Clinical Research Institute

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 core metrics of quality, reliability, compatibility, capabilities, and expertise, these attributes were what our readers identified as being most important, and as such, we felt it was important to share the data with other sponsor companies.

DATA QUALITY

TOP PERFORMERS

CHDR
BIOTRIAL
SGS Life Science Services
Novotech

EXCEEDED CUSTOMER EXPECTATIONS

Eurofins
Worldwide Clinical Trials
CRS Clinical Research Services Andernach GmbH
DaVita Clinical Research
PPD
Duke Clinical Research Institute
Covance
Inamed
Eurotrials
WCCT Global
US Oncology
Quintiles
Vince & Associates Clinical Research
ProTrials
Medpace
Celerion
Quotient Clinical
Chiltern
Lambda Therapeutic Research
INC Research
PRA

MEETING OVERALL PROJECT TIMELINES

TOP PERFORMERS

BIOTRIAL
CRS Clinical Research Services Andernach GmbH

EXCEEDED CUSTOMER EXPECTATIONS

SGS Life Science Services
Quotient Clinical
Chiltern
Pharm-Olam International
Novotech
Algorithme Pharma
Eurofins
Lambda Therapeutic Research
Worldwide Clinical Trials
Medpace
Tata
Eurotrials
DaVita Clinical Research
Covance
Medsource
CHDR

OFFERED INNOVATIVE SOLUTIONS

TOP PERFORMERS

Vince & Associates Clinical Research
CRS Clinical Research Services Andernach GmbH
CHDR
Quotient Clinical

EXCEEDED CUSTOMER EXPECTATIONS

BIOTRIAL
Eurofins
Celerion
SGS Life Science Services
Tata
US Oncology
DaVita Clinical Research
Lambda Therapeutic Research
Inamed
Bioskin
PPD
Quintiles
Eurotrials
Duke Clinical Research Institute
Covance
TKL Research
Medpace
Accelovance

CRO LEADERSHIP AWARDS

INDIVIDUAL ATTRIBUTE AWARDS

OPERATIONAL EXCELLENCE

TOP PERFORMERS

CRS Clinical Research Services Andernach GmbH
CHDR

EXCEEDED CUSTOMER EXPECTATIONS

BIOTRIAL
SGS Life Science Services
Worldwide Clinical Trials
Eurofins
Eurotrials
Tata
US Oncology
Chiltern
WCCT Global
Medpace
Quintiles
PPD
Covance
DaVita Clinical Research
Celerion
PRA
Bioskin
ProTrials
Quotient Clinical
INC Research
Pharm-Olam International
Rho
Lambda Therapeutic Research

RESPONSIVENESS

TOP PERFORMERS

Pharm-Olam International
BIOTRIAL

EXCEEDED CUSTOMER EXPECTATIONS

Worldwide Clinical Trials
SGS Life Science Services
CRS Clinical Research Services Andernach GmbH
Vince & Associates Clinical Research
Medpace
QPS
Eurofins
Quotient Clinical
Tata
Chiltern
PPD
Lambda Therapeutic Research
Rho
SynteractHCR
Covance
INC Research
US Oncology

TECHNOLOGY FOR REAL-TIME ACCESS TO DATA

TOP PERFORMERS

CHDR
Vince & Associates Clinical Research
BIOTRIAL

EXCEEDED CUSTOMER EXPECTATIONS

Eurofins
CRS Clinical Research Services Andernach GmbH
Bioskin
Eurotrials
Accelovance
Inamed
Quintiles
US Oncology
PPD
Covance
SGS Life Science Services
Tata
SynteractHCR
Quotient Clinical
Worldwide Clinical Trials
NAMSA
PAREXEL
Pharm-Olam International
Duke Clinical Research Institute

CATEGORIES WON

Algorithme Pharma

Laval, Québec, Canada
www.altasciences.com

+1 450 973 6077
Cathy Konidas
ckonidas@altasciences.com
Key locations: Laval, Québec, Canada; Montréal, Québec, Canada; Fargo, North Dakota, U.S.A.

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2)
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: healthy norm. vols., spec. populations, proof-of-concept, adap. design, SAD/MAD, bioavail./bioequiv., PK/PD, dose ranging, biosimilars, lg/sm mol. bioanalysis, data mgmt., biostatistics, reg. support, proj. mgmt.

THERAPEUTIC AREAS: allergy, CV, CNS, cog. testing, dermatology, diabetes, EEG, GI, hematology, hepatitis, metabolic disorders, nephrology, obesity, ophthalmology, pain/inflammation, psychiatry, post-menopausal women, pul., women's health, vaccines

INDIVIDUAL ATTRIBUTE AWARDS: meeting overall project timelines

CHRIS PERKIN
CEO

"We are honored to have been recognized as a leader in the CRO industry. Our mission has always been to provide the highest quality early stage clinical development solutions, while exceeding our customers' expectations with personalized and timely service. These awards recognize and validate the efforts our employees put in on a daily basis to achieve our goals. I am extremely proud of our team."

CATEGORIES WON

Bioclinica

Doylestown, PA
www.bioclinica.com

+1 267 757 3000
Chris Englerth
Chris.englerth@bioclinica.com
Key locations: Doylestown, PA; Audubon, PA; Princeton, NJ; Miami, FL; U.S.A.; London, UK; Shanghai, China; Tokyo, Japan

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: research network, patient recruitment-retention, post-approval research, eClinical solutions, safety & regulatory solutions, financial life cycle solutions, medical imaging, cardiac safety, molecular marker laboratory

THERAPEUTIC AREAS: oncology, neuroscience, musculoskeletal, cardiovascular, metabolic and endocrinology, inflammatory

JOHN HUBBARD
President & CEO

"Clinical trials are complex, and the most successful trials require the ability to see key details and uncover hidden insights. Bioclinica creates clarity in the clinical trial process – so our customers can make better decisions. We are utilizing data, analytics, and technology to enable more efficient trial conduct, improve the efficiency of clinical trial centers, provide greater clarity into the therapeutic effect of the drug, and to reduce risk in the clinical trial process."

CATEGORIES WON

BIOTRIAL

Newark, NJ
www.biotrial.com

+1 973 388 2448
Xavier Martin
xavier.martin@biotroial.com
Key locations: Rennes, France; Mulhouse, France; Newark, NJ, U.S.A; London, UK; Montreal, Canada

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

MAIN SERVICE AREAS:
Preclinical, Full Service Clinical

SERVICES & CAPABILITIES: nonclinical pharmacology, early clinical dev., bioanalysis, Phase II patient studies, translational oncology, ECG, CNS, & imaging core lab, data mgmt., biostatistics, PK & medical writing

THERAPEUTIC AREAS: healthy volunteers, special populations (elderly, postmenopausal women), hepatic & renal, impairment, slow/rapid metabolizers, oncology patients, CNS diseases, infectious diseases, rheumatoid arthritis, metabolic CV, & respiratory diseases

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

JEAN-MARC GANDON
President & CEO

"Biotrial was founded with the idea that in order to help develop medications for patients who need them, pharma and biotech companies need not only subcontractors, but rather partners they can count on to bring them scientific, medical, and operational expertise. Throughout our history we have strived to remain faithful to this idea and our sponsors have shown us the value they attach to such an approach."

CATEGORIES WON

Celerion

Lincoln, NE
www.celeron.com

+1 402 476 2811
David Maya
david.maya@celerion.com
Key locations: Lincoln, NE; Phoenix, AZ; Belfast, Northern Ireland UK; Zurich, Switzerland; Montreal, Quebec, Canada; Vienna, Austria; Berlin, Germany; Seoul, South Korea

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

MAIN SERVICE AREAS:
Lab, Full Service Clinical

SERVICES & CAPABILITIES: Celerion conducts first-in-human, clinical proof-of-concept & dose response in patients, cardiovascular safety, & NDA-enabling clinical pharmacology studies. Support is also provided in statistics, PK/PD analysis, & small/large molecule bioanalytical services.

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

INDIVIDUAL ATTRIBUTE AWARDS: data quality, offered innovative solutions, operational excellence

SUSAN THORNTON
President & CEO

"It is an honor to have our clients recognize us with these awards. Celerion delivers Applied Translational Medicine to help our clients generate key data very early and enable faster go/no-go decisions. With over 40 years of experience, scientific expertise, clinical capabilities, and bioanalytical laboratories, Celerion provides global innovative solutions in support of complex studies in healthy subjects and patients. These awards reinforce our commitment to responding to our clients' challenges in drug development."

CATEGORIES WON

Chiltern

Wilmington, NC
www.Chiltern.com

+1 910 338 4760
Christine Wigert
Lets.Talk@Chiltern.com
Key locations: United States, United Kingdom, Asia-Pacific, Central and Eastern Europe, Latin America, Middle East, North Africa

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: clinical development, clinical supplies, data & analysis, medical, regulatory & pharmacovigilance, & strategic service provision

THERAPEUTIC AREAS: anti-infectives & vaccines, cardiovascular, cell therapy, central nervous system, dermatology, endocrinology, inflammation, oncology, ophthalmology, orthopedics, radiology & nuclear medicine, respiratory, & women's health

INDIVIDUAL ATTRIBUTE AWARDS: data quality, meeting overall project timelines, operational excellence, responsiveness

DR. JIM ESINHART
CEO

"We are proud to be recognized by our peers as one of the top CROs in the industry. We are the only CRO to be awarded in five overall categories five years in a row. This is a testament to our commitment to building strong collaborative partnerships and striving for clinical excellence. We will continue to work hard for our clients and provide top-level performance going forward."

CATEGORIES WON

Covance Inc.

Princeton, NJ
www.Covance.com
+1 609 452 4440 or + 00 800 2682 2682

Jared Freedberg
jared.freedberg@covance.com
Key locations: Brazil, China, Germany, Russia, Singapore, Switzerland, United Kingdom, United States

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)

MAIN SERVICE AREAS:
Lab, Preclinical, Full Service Clinical

SERVICES & CAPABILITIES: research, lead optimization, analytical services, safety assessment, consulting, clinical development, clinical testing, commercialization, & manufacturing support

THERAPEUTIC AREAS: inflammation, oncology, cardiovascular/metabolic, neuroscience, infectious disease, analgesic, anti-infectives, CNS, dermatology, GI, hematology, hormonal therapy, immunology, ocular, renal disease, & respiratory disease

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

DEB KELLER
CEO

"We pride ourselves in delivering high-quality solutions that meet our clients' needs within each phase of drug development, from preclinical testing to regulatory approval and beyond. Through the power of LabCorp, those solutions have expanded to include development of industry-leading capabilities in informatics, companion diagnostics, patient recruitment, and other technologies that will improve success, reduce the time and cost of trials, and bring new and innovative medicines to patients even sooner."

CRS Clinical Research Services

CATEGORIES WON

CRS Clinical Research Services Andernach GmbH

Andernach, Germany
www.crs-group.de

+49 2632 992784
David Surjo
david.surjo@crs-group.de
Key locations: Mannheim, Mönchengladbach, Kiel, Lübeck, Berlin, Wuppertal; Germany

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: complete range of high-quality clinical trials from FIM to POC trials plus trial specialties

THERAPEUTIC AREAS: thorough QTc trials according to the ICH E14 guideline in coop. w/ various central ECG labs; pharmacodynamics trials w/ GI, CNS, CV, & pneumological focus; renal & hepatic impairment PK; dermal expertise/skin safety; clin. conduct of trials in a univ. hospital setting; women's health incl. gynecological examinations; resp. trials

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

TORBEN THOMSEN
Partner, President & CEO

"I am very proud that our efforts to achieve highest client satisfaction are recognized by these awards. This appreciation is based on our experience and know-how built up over four decades in clinical research. To be leading in all core categories confirms our continuous strive for excellence. The outstanding quality and reliability is reflected by the high number of satisfied clients who repeatedly entrust CRS with the conduct of phase I/II clinical trials."

DaVita Clinical Research

CATEGORIES WON

DaVita Clinical Research (DCR)

Minneapolis, MN
www.DaVitaClinicalResearch.com

+1 612 852 7000
Kevin Goudreau
Kevin.Goudreau@DaVita.com
Key locations: Minneapolis, MN; Denver, CO; Los Angeles, CA; Las Vegas, NV; Houston, TX; New York, NY; Colorado Springs, CO; 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 clinical trials, including medical writing & data mgmt.; Phase 2b-4 clinical trials & site network; medical comm.; de-identified patient datasets, including EHRs, claims, Rx & lab data

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

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

AMY YOUNG
Vice President & General Manager

"As a wholly-owned subsidiary of a large 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 enables 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."

Duke Clinical Research Institute
From Thought Leadership to Clinical Practice

CATEGORIES WON

Duke Clinical Research Institute

Durham, NC
www.dcri.org

+ 1 919 668 8700
Suzanne Pfeifer
suzanne.pfeifer@duke.edu
Key location: Durham, NC

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: adv. biomarkers, biostatistics, clin. events class., data mgmt., ECG, imaging, med. comm., pharmacometrics, proj. leadership, reg. svcs. safety surv., site mgmt. & clin. monitoring

THERAPEUTIC AREAS: cardiology, hepatology/GI, geriatrics, metab. bone dis., hematology, immun. & inflamm., infect. diseases, nephrology, neurosciences (CNS: psychiatry & neurology), oncology, ophth., otolaryngology, peds., perioperative, PC, pulmonary, transplant, wmn's health

INDIVIDUAL ATTRIBUTE AWARDS: data quality, offered innovative solutions, technology for real-time access to data

ERIC PETERSON
Executive Director

"For more than 30 years, the DCRI has been dedicated to advancing clinical research through innovative study design and operations, thoughtful interpretation of data, and a commitment to the rapid translation of knowledge into practice. We are addressing the challenges patients, clinicians, and sponsors face while offering insights, ideas, and direction for the future."

Eurofins Scientific

CATEGORIES WON

Kraainem, BELGIUM
www.eurofins.com

+1 717 656 2300 or +32 2 766 16 20
Dirk Bontridder
pharma@eurofins.com
Key locations: Lancaster, PA; Seattle, WA; Louisville, KY; Framingham, MA; U.S.A.; Munich, Germany; Milan, Italy; Sydney, Australia; Tokyo, Japan

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Logistics

MAIN SERVICE AREAS:
Lab, Preclinical, Full Service Clinical

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

THERAPEUTIC AREAS: Eurofins supports all therapeutic areas within the bio/pharma & medical device industries.

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

DR. GILLES MARTIN
CEO

"It is an honor to receive the CRO Leadership Award in all five categories. At Eurofins, we work extremely hard every day to transform our scientific excellence, comprehensive service offerings, and dedication to quality into an outstanding service experience for our clients. We are pleased that the bio/pharmaceutical industry continues to recognize Eurofins as a leader in these key areas."

Eurotrials

Scientific Consultants

CATEGORIES WON

Lisbon, Portugal
www.eurotrials.com

+ 351 21 382 54 40
Rui Melo
rui.melo@eurotrials.com
Key locations: Argentina, Brazil, Chile, Mexico, Peru, Portugal, Spain, France

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: international phase II, III & IV studies, FSP /placements, EAP, IIS, BA/BE, proj. mgmt. study monitoring, epidemiology, observational studies, health economics, biostatistics, data mgmt., quality, reg. affairs, pharmacovigilance, medical writing

THERAPEUTIC AREAS: cardiology, oncology, neurology, infectious diseases, endocrinology, urology, rheumatology, dermatology, respiratory diseases

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

MARIA JOÃO QUEIROZ
Global CEO & Founder

"With its 20 years of existence, Eurotrials has asserted itself as a partner of reference for clinical and translational research in the area of health in Europe and Latin America. We want to continue to expand our presence in these two regions, whilst consolidating our position in these markets. We thank our collaborators for all their support in making these types of achievements possible."

INC Research

CATEGORIES WON

Raleigh, NC
www.incresearch.com

Christian Tucat
Christian.Tucat@INCResearch.com
Key locations: Australia, Canada, China, Mexico, Japan, UK, U.S.A.

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: alliance partners, biometrics, clin. data mgmt., contracts/funct. svcs., drug safety, funct. svc. prov. partners, med. monitor, med. writing, pt. recruit./reten., proj. mgmt., QA, reg. affairs, strat. consulting, study monitor.

THERAPEUTIC AREAS: biometrics, biosimilars, CV, CNS, early phase, endocrinology, GE/hepatology, hematology immun. & inflamm., infect. disease, oncology, ophthalmology, peds., respiratory, women's health

INDIVIDUAL ATTRIBUTE AWARDS: data quality, operational excellence, responsiveness

JAMIE MACDONALD
CEO

"INC Research is honored to be recognized among *Life Science Leader's* CRO Leadership award winners for 2016. We blend significant experience across Phase I to IV clinical development along with strong therapeutic focus and industry-recognized site relationships to accelerate the delivery of new medicines to market for patients. Our focus is on continuing to deliver value to our customers as an innovative, forward-thinking clinical development partner in the evolving healthcare landscape."

CATEGORIES WON

inVentiv Health

Princeton, NJ
www.inventivhealth.com

+1 800 416 0555 or +44 (0) 207 632 1800
Greg Skalicky
Clinical.Information@inVentivHealth.com
Key locations: Burlington, MA; Princeton, NJ; Blue Bell, PA; New York, NY; Maidenhead, London; Seoul, Korea; Shanghai, China; Tokyo, Japan

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

MAIN SERVICE AREAS:
Lab, Full Service Clinical

SERVICES & CAPABILITIES: A professional services organization, we accelerate the success of biopharmaceutical companies worldwide. Our combined Clinical Research & Contract Commercial Organizations help improve clients' performance to deliver much-needed therapies.

THERAPEUTIC AREAS: therapeutically aligned project teams & expertise in virtually all therapeutic areas includ. oncology/hematology, neuroscience, pain, general medicine, cardiovascular, infectious diseases/vaccines, rare diseases

MICHAEL MCKELVEY
Executive VP, inVentiv Health & President, inVentiv Health Clinical

"We are honored to have been selected this year for Big Pharma 'COMPATIBILITY' and 'QUALITY' and proud to say we work closely with all Top 20 Pharma. In today's challenging business environment, success is no longer measured by drug approval alone – rather by market access and availability. At inVentiv we've built a comprehensive outsourcing model including clinical and commercial expertise our clients rely on, no matter where they are in their product's lifecycle."

CATEGORIES WON

PAREXEL International

Waltham, MA
www.PAREXEL.com

+1 781 487 9900
David Godwin
David.Godwin@PAREXEL.com
Key locations: The Americas, Europe/Middle East/Africa, Asia/Pacific

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Formulated Drug Production: Packaging, Logistics

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: expertise-based contract research, consulting, & technology solutions across the drug development & commercialization continuum, including clinical research, clinical pharmacology, clinical trial management, clinical logistics, regulatory consulting, & commercialization consulting services

THERAPEUTIC AREAS: PAREXEL has expertise across a broad range of therapeutic areas including oncology, hematology, pulmonology, metabolism/endocrine, & infectious disease.

INDIVIDUAL ATTRIBUTE AWARDS: technology for real-time access to data

JOSEF VON RICKENBACH
Chairman & CEO

"PAREXEL is honored to be recognized by the biopharmaceutical industry with a 2016 *Life Science Leader* Leadership Award. These awards validate our mission to combine the strength of our expertise, experience, and innovation to advance the success of our clients in preventing and curing disease. This award also celebrates our employees: Guided by the principles of quality, initiative, and teamwork, our people help ensure that our clients can bring their new drug treatments to patients."

CATEGORIES WON

Pharm-Olam International

Houston, TX
www.pharm-olam.com

+1 713 559 7900 or +44 (0) 1344 891121
Mark Eberhardt
mark.eberhardt@pharm-olam.com
Key locations: Houston, TX; Ascot, UK; 29 staffed offices covering 40 countries

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: regulatory, proj. mgmt., clin. ops., patient recruit., feasibility, rescue enrollment, site mgmt., med. affairs, med. monitoring, pharmacovigilance, medical writing, data mgmt., biostatistics, QA/QC

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

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

DR. ZEV MUNK
Chairman of the Board

"At Pharm-Olam we understand that our client's clinical trials are critical stages of a major research and development investment and hold the promise of bringing relief, better health, more effective therapies, or longer life to patients across the globe. I believe that our flat organizational structure, flexibility, commitment to quality, and experienced team were key components to us being selected, and on behalf of the entire Pharm-Olam team, we are honored to receive this award."

PPD

CATEGORIES WON

Wilmington, NC
www.ppdi.com

+1 910 251 0081
PPD Business Development
ppdinfo@ppdi.com
Key locations: Operations in 46 countries, including in Wilmington, NC; Research Triangle, NC; Madison, WI; Austin, TX; Europe; China; Japan; Latin America.

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, 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 & vaccines & biologics labs, biomarker svcs. Consulting svcs: prod. dev., biosimilars, adaptive trial design, pediatrics, rare diseases, cardiovascular outcomes, medical devices

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

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

DAVID SIMMONS
Chairman & CEO

"PPD's purpose and mission are to improve health by helping our customers deliver life-changing therapies. Our strategy of bending the cost and time curve of drug development gets therapies to patients faster and improves the productivity of our customers' R&D investments. As our customers' needs continue evolving, we remain committed to continuous improvement and innovation to address the difficult challenges affecting the biopharmaceutical industry in our shared mission of delivering life-changing medicines to improve health."

PRA Health Sciences

CATEGORIES WON

Raleigh, NC
www.prahs.com

+1 919 786 8200
Roger Boutin
BoutinRoger@prahs.com
Key locations: Raleigh, NC, Blue Bell, PA, U.S.A.; Victoria, BC, Canada; Buenos Aires, Argentina; Johannesburg, South Africa; Zuidlaren/Assen/Groningen, The Netherlands; Moscow, Russian Federation; Singapore

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Formulated Drug Production: Logistics

MAIN SERVICE AREAS:
Lab, Full Service Clinical

SERVICES & CAPABILITIES: Innovative full-service clinical & staffing solutions across all phases & therapeutic areas. Providing coverage across 80+ countries, we bolster our impressive global presence with local insights.

THERAPEUTIC AREAS: neurology & psychiatry (CNS), oncology/hematology, infectious diseases, cardio-metabolic, rare diseases, vaccines, respiratory, genitourinary, endocrinology, gastroenterology, immunology, hepatology, dermatology & biosimilar products

INDIVIDUAL ATTRIBUTE AWARDS: data quality, operational excellence

COLIN SHANNON
President & CEO

"PRA Health Sciences is delighted to once again receive these awards. This recognition is a tribute to our dedicated employees who continually seek new and innovative ways to transform clinical development and bring life-saving medicines to patients who need them."

QPS Holdings, LLC

CATEGORIES WON

Newark, DE
www.qps.com

+1 512 350 2827
Lily Rosa
lily.rosa@qps.com
Key locations: Newark, DE; Springfield, MO; Fargo, ND; Research Triangle Park, NC; Hollywood, FL; South Miami, FL, USA; Groningen, The Netherlands; Graz, Austria; Hyderabad, India; Barcelona, Spain; and Taipei, Taiwan

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)

MAIN SERVICE AREAS:
Lab, Preclinical, Full Service Clinical

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); oncology; & many more therapeutic indications

INDIVIDUAL ATTRIBUTE AWARDS:
responsiveness

BEN CHIEN
Chairman, President & CEO

"I am absolutely thrilled that out of 65 candidate companies, QPS has again received a CRO Leadership Award–specifically in the core categories of compatibility, expertise, quality, and reliability. Honestly, I am not surprised – I know how hard QPS employees have worked all year. They are passionate about their work and take pride in providing our customers with the most responsive, proactive, respectful, and high-quality service possible. I am proud of their accomplishment."

Quintiles

CATEGORIES WON

Quintiles

Durham, NC
www.Quintiles.com

+1 919 998 2000
Chris Cabell
christopher.cabell@quintiles.com

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

MAIN SERVICE AREAS:
Lab, Full Service Clinical

SERVICES & CAPABILITIES: advisory services, clinical trial execution, phase I/IIa & early clinical trials, phase II/III clinical trials, clinical monitoring, project management, regulatory affairs, central laboratories, real-world late phase, contract sales, market access

THERAPEUTIC AREAS: acute care & pain, allergy & respiratory, cardiovascular, central nervous system, diabetes, immunology, infectious diseases, internal medicine, oncology, pediatrics, public health interest, rare disease, vaccines

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

CYNTHIA VERST
President, Clinical Operations, PharmD, MS

"Today's interconnected, global healthcare ecosystem is increasingly complex and requires a great degree of scale, specialization, and efficiency to be successful. This award recognizes Quintiles' leadership in the industry and is built upon the foundation of our passionate employees whose high-quality delivery, expertise, and capabilities are so critical to improving patient outcomes as well as our customers' probability of success."

Rho, Inc.

CATEGORIES WON

Rho, Inc.

Chapel Hill, NC
www.rhoworld.com

+1 919 408 8000
Joan Parks
info@rhoworld.com
Key location: Chapel Hill, NC

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: consulting, functional service provider model, phase I, phase II/III, post-approval, regulatory submissions, trial rescue, biostatistics & statistical programming, clinical data management, clinical operations & monitoring, clinical project management

THERAPEUTIC AREAS: ADHD, analgesia, CNS, dental, hematology, ophthalmology, psychiatric disorders, respiratory

INDIVIDUAL ATTRIBUTE AWARDS: operational excellence, responsiveness

RUSS HELMS
CEO

"At Rho, we believe that if we are successful, it's because we're agile. We react quickly to change but always stay focused on serving our customers instead of ourselves."

SynteractHCR

CATEGORIES WON

SynteractHCR

Carlsbad, CA
www.SynteractHCR.com

+1 760 268 8200
Matt Smith
matt.smith@synteracthcr.com
Key locations: Carlsbad, CA, Morrisville, NC, U.S.A; Munich, Germany; Brussels, Belgium; Barcelona, Spain; Paris, France; Warsaw, Poland; Moscow, Russia; Cambridgeshire, U.K.

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: project management, clinical operations, data management, CDISC expertise, IWRS, medical and regulatory affairs, medical writing, biostatistics

THERAPEUTIC AREAS: SynteractHCR has broad therapeutic experience including a notable depth in cardiovascular, CNS, endocrinology, immunotherapy, infectious disease, oncology, ophthalmology, pediatrics, & respiratory.

INDIVIDUAL ATTRIBUTE AWARDS:
responsiveness, technology for real-time access to data

WENDEL BARR
CEO

"We are honored to be recognized again this year as a leading full-service CRO. Supporting our biotech and medical device clients is an exciting endeavor. We take seriously the trust they give us to deliver the services they want. As we have for over two decades, we strive to consistently deliver the highest quality of service to help bring tomorrow's treatments to the patients who need them. We thank Life Science Leader for this recognition."

Altasciences
CLINICAL RESEARCH
VINCE & ASSOCIATES

CATEGORIES WON

Vince & Associates Clinical Research

Overland Park, KS
www.vinceandassociates.com

+1 913 696 1601
Julie-Ann Cabana
jcabana@vinceandassociates.com
Key location: Overland Park, KS

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: phase I-II, healthy norm. vols., spec. populations, proof-of-concept, adapt. design, FIH, SAD/MAD, bioavail./bioequiv., PK/PD, dose ranging, food effect, QT/QTc, biosimilars, human abuse liability/substance abuse

THERAPEUTIC AREAS: allergy, CV, CNS, cog. testing, derm., diabetes, EEG, elderly, GI, hematology, hepatitis, mtd./bup., metabolic disorders, obesity, ophth., pain/inflammation, peds., psychiatry, post-menopausal, pul., sleep disorders, substance abuse, wmn's health, vaccines

INDIVIDUAL ATTRIBUTE AWARDS: data quality, offered innovative solutions, responsiveness, technology for real-time access to data

BRAD VINCE
CEM & Medical Director

"This acknowledgment is a true testament to the hard work, experience, and commitment that our dedicated employees put forth each and every day. The awareness of our pharma and biotech clients of our quality and excellence is what motivates us to continue to set a new standard in early development clinical trials."

WORLDWIDE CLINICAL TRIALS

CATEGORIES WON

Worldwide Clinical Trials

Morrisville, NC
www.Worldwide.com

+1 919 674 2900 or 44 (0) 207 121 61 61
Chris Crucitti
chris.crucitti@worldwide.com
Key locations: Austin, TX; King of Prussia, PA; Morrisville, NC; U.S.A.; Belgrade, Serbia; London and Nottingham, UK; St. Petersburg, Russia; Kiev, Ukraine

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

MAIN SERVICE AREAS:
Lab, Full Service Clinical

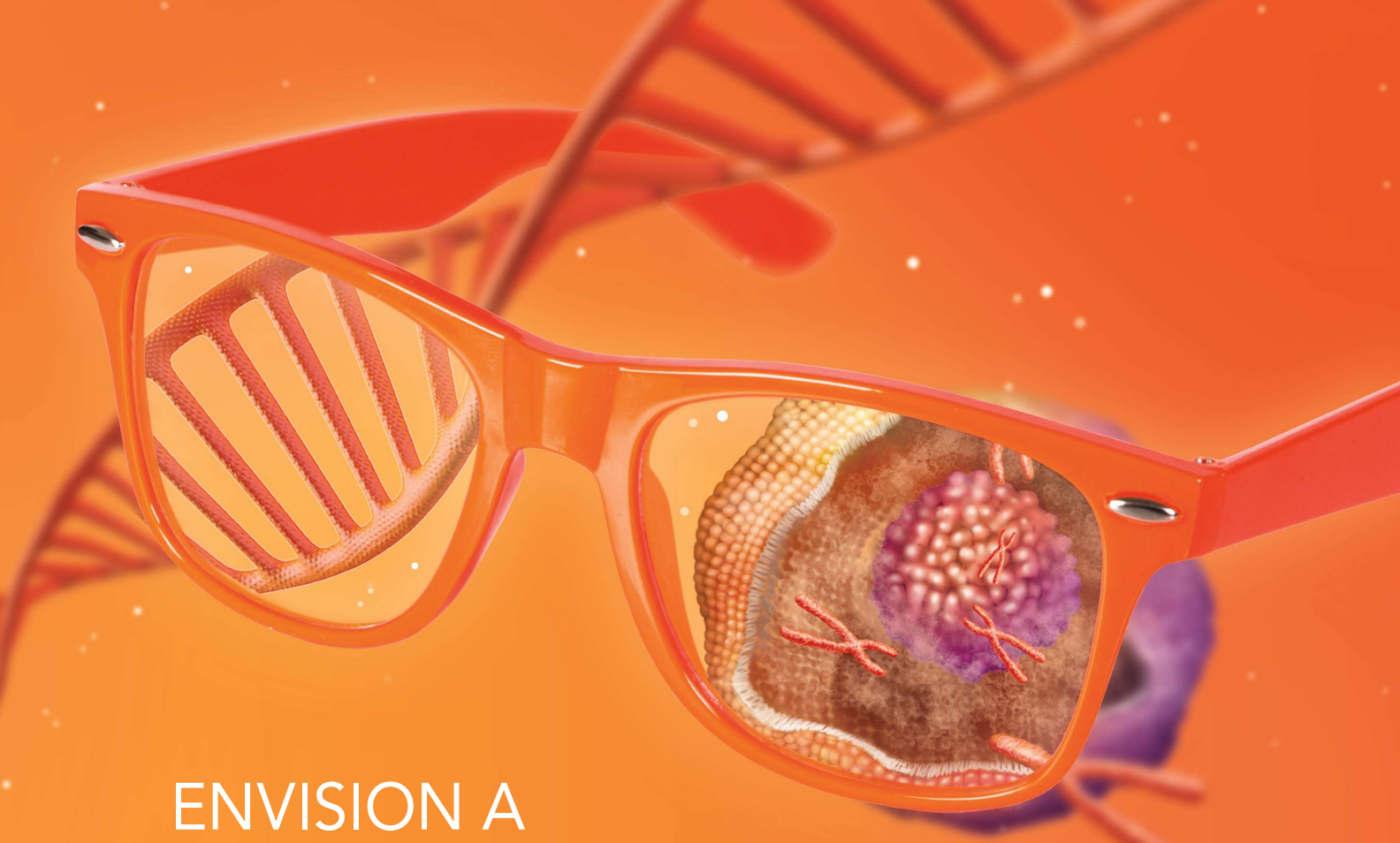
SERVICES & CAPABILITIES: a full-service contract research organization, we partner with sponsors to deliver fully integrated clinical research, clinical development & bioanalytical services, extending from first-in-human through phase IV studies.

THERAPEUTIC AREAS: Worldwide Clinical Trials supports 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, operational excellence, responsiveness, technology for real-time access to data

PETER BETON
President & COO

"To be recognized with CRO Leadership Awards for the third year running is a reflection of the talent, commitment, and expertise of our 1,400 employees around the world. Grounded in medicine and science, our team is dedicated to developing close, trusting partnerships with our sponsors. It's our privilege to support sponsors as they move from medical discovery into clinical development and commercialization, bringing innovative solutions to market that deliver enhanced value and improve patient lives."



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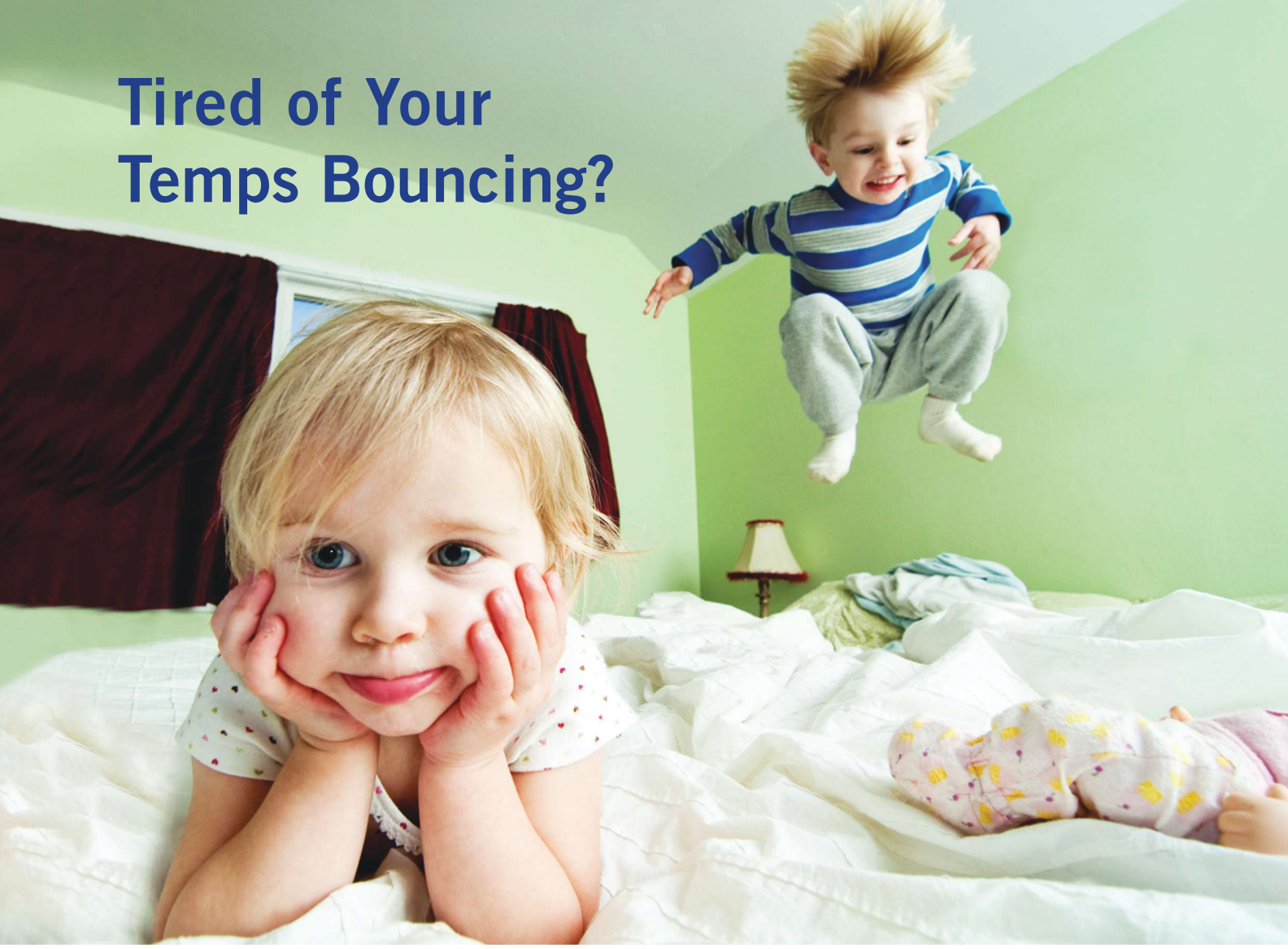

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