A Supplement to
Life Science Leader
The Industry's Essential Business Source
MARCH 2014

The Future

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Life Science Leader

The Industry's Essential Business Source

MARCH 2014

The Future of Outsourced Clinical Trials

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Meet the 2014 CRO Leadership Award Winners!

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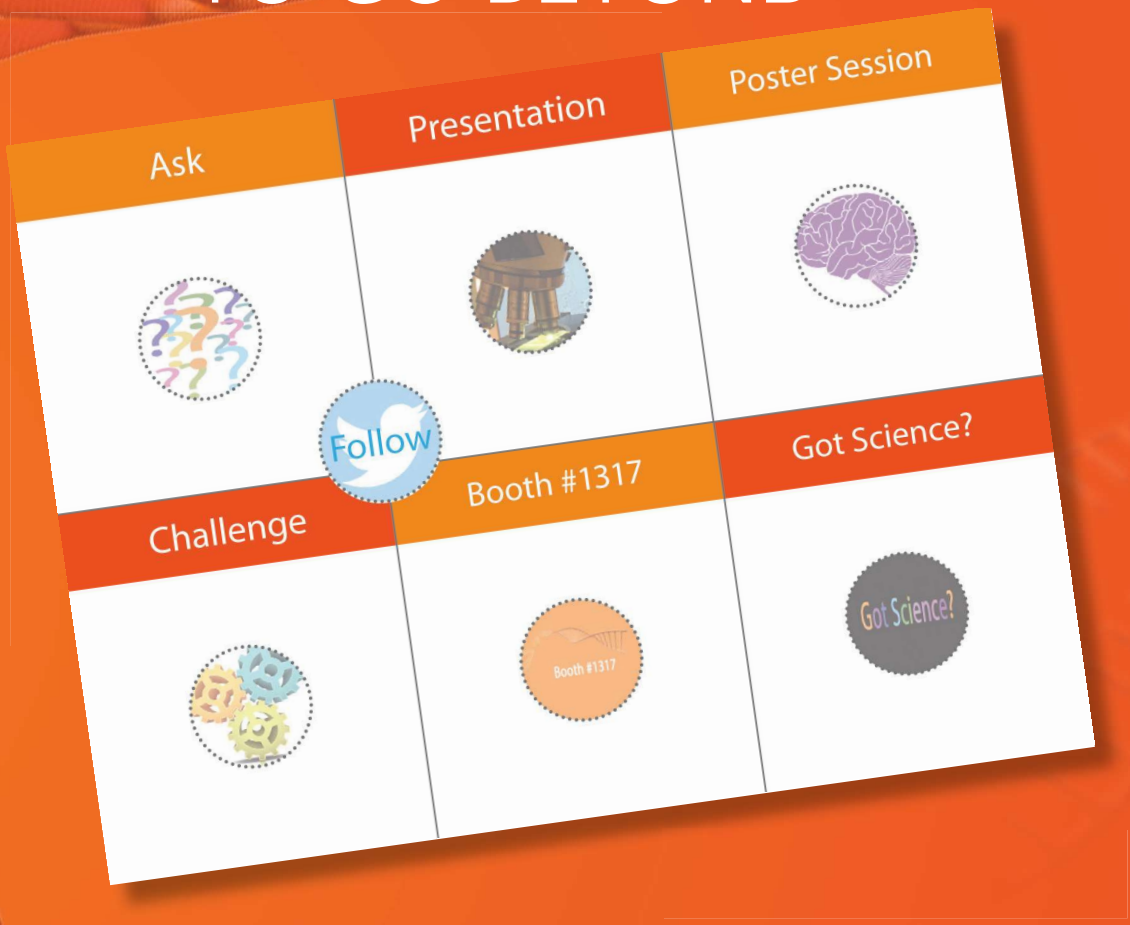

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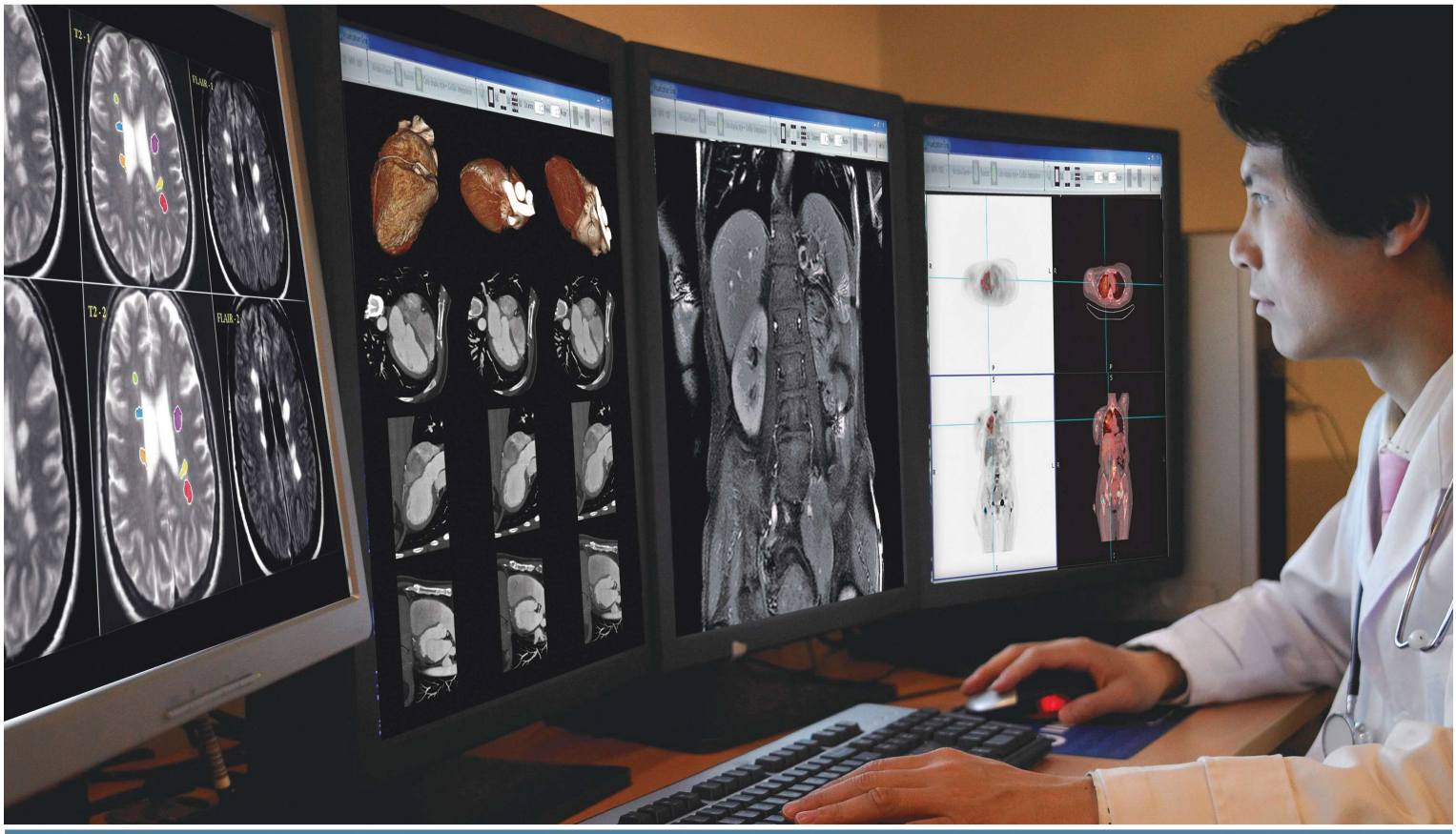

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At *Life Science Leader* magazine, it is our pleasure to announce the third annual 2014 CRO Leadership Awards winners. Unlike other award programs where there can be only one winner per category, our awards list all the CROs that scored in the top 20 percent for the following categories — quality, reliability, innovation, productivity, and regulatory. Furthermore, there is not an overall CRO leadership award winner. Let me explain why we've taken this approach.

Life Science Leader's annual CRO Leadership Awards are determined by industry-leading market research conducted by Nice Insight. More than 40,000 pharmaceutical and biopharmaceutical executives responsible for making or influencing their company's outsourcing decisions are invited to participate in Nice Insight's annual survey. This year's survey received over 10,000 responses. To be clear, the survey is not a solicitation for respondents to nominate their "favorite" CRO for an award. Rather, the survey is designed to gather a wide variety of industry-related information. Responses are compiled and analyzed to identify awareness and perception scores for CROs serving the pharmaceutical and biopharmaceutical industry. Thus, *Life Science Leader* magazine's CRO Leadership Awards don't involve a nomination, ballot, or judging process. There is no "entry fee" required to participate. There is no award-processing fee stating, "Congratulations on winning. To claim your award, please send a check in the amount of ____ to cover the cost of shipping and handling." We don't require award winners to advertise. Heck, we don't even charge the award-winning CROs for the alphabetical listing which details their services and contact information in our magazine! You may be wondering, if not to make money, then why do we do it? Well, feedback from *Life Science Leader's* executive-level readers indicates a high level of confusion among executives regarding CRO selection approaches and, consequently, a strong desire for information on what their peers think of a wide range of CROs. This leads me to a reader-driven change for the awards this year. Not all pharma and biopharm companies look alike or function alike. Emerging bio companies have different needs and goals than Big Pharma does and vice versa. We have separated the response data into four segments: Big Pharma, emerging pharma, biotech, and emerging biotech. Now the companies in these segments can see what their peers in the same segment think of the CROs in each perception category. This data can then help steer them to CROs that have experience with their type of company.

Last year, I received a number of emails and phone calls regarding the announcement of the 2013 CRO Leadership Awards. Winners were understandably skeptical. It is a rare thing for a company to develop an awards program that doesn't have some sort of strings attached. It is even rarer to create an award free of undue influence. Nevertheless, this is exactly what we have tried to do at *Life Science Leader* magazine. So join me in congratulating all of this year's CRO Leadership Award winners! It's a job well done and well deserved. You've *earned* it.

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LIFE SCIENCE LEADER
2591 Wexford-Bayne Rd.
Bldg. II, Level 3, Ste. 305
Sewickley, PA 15143-8676

Telephone: +1 724 940 7557
Fax: +1 724 940 4035

WWW.LIFESCIENCELEADER.COM

VP OF PUBLISHING
Jon Howland
814 897 9000 / Ext. 203
jon.howland@lifescienceleader.com

CHIEF EDITOR
Rob Wright
814 897 9000 / Ext. 140
rob.wright@lifescienceconnect.com

EXECUTIVE EDITOR
Wayne Koberstein
wayne.koberstein@lifescienceleader.com

EDITORIAL DIRECTOR
Dan Schell
814 897 9000 / Ext. 284
dan.schell@lifescienceleader.com

PRODUCTION DIRECTOR
Lynn Netkowicz
814 897 9000 / Ext. 205
lynn.netkowicz@jamesonpublishing.com

DIRECTOR OF AUDIENCE DEVELOPMENT
Mindy Fadden
814 897 9000 / Ext. 208
mindy.fadden@jamesonpublishing.com

PUBLISHER, CLINICAL & CONTRACT RESEARCH
Sean Hoffman
724 940 7557 / Ext. 165
sean.hoffman@lifescienceleader.com

ASSOC. PUBLISHER/BIOPHARM & LAB
Shannon Primavere
814 897 7700 / Ext. 279
shannon.primavere@lifescienceleader.com

PUBLISHER/OUTSOURCING
Cory Coleman
814 897 7700 / Ext. 108
cory.coleman@lifescienceleader.com

GROUP PUBLISHER/OUTSOURCING
Ray Sherman
814 897 7700 / Ext. 335
ray.sherman@lifescienceleader.com

BUSINESS DEVELOPMENT MANAGER
Mike Barbalaci
814 897 7700 / Ext. 218
mike.barbalaci@lifescienceleader.com

SR. ACCOUNT EXECUTIVE
Scott Moren
814 897 7700 / Ext. 118
scott.moren@lifescienceleader.com

ACCOUNT EXECUTIVE, PACKAGING & SERIALIZATION
Evan Lagacé
814 897 7700 / Ext. 119
evan.lagace@lifescienceleader.com


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How To Improve Clinical Trials –

Some Good Old-Fashioned Wisdom

ROB WRIGHT Chief Editor

Intel cofounder Gordon Moore predicted in 1965 that the number of transistors on an integrated circuit would double approximately every two years. What came to be known as **Moore's Law** has basically held true ever since.

The reciprocal effect of this increased microchip performance is decreased computer costs. Similar economic gains have been made in other information-intensive industries (e.g. telecommunications). Unfortunately, the same relationship does not exist for clinical trials, which have witnessed steady cost increases of 7.4 percent annually over inflation for the past 20 years — despite the advent of various technologies (e.g. electronic health records and electronic data collection) that significantly reduce the amount of time and effort required to gather clinical data.

In a discussion paper (April 13, 2012) presented to the Institute of Medicine's Forum on Drug Discovery, Development, and Translation, Duke University Medical Center researchers Judith Kramer, M.D., and Kevin Schulman, M.D., note that the problem with escalating clinical trial costs is the result of sponsors, CROs, regulatory agencies, and providers failing to evolve the clinical research business model to keep pace with advances in technology. As a result, rising clinical trial costs have played a pivotal role in skyrocketing drug development costs.

Performing clinical trials as they have been done for decades is no longer acceptable. Technological and methodological advances have afforded sponsors the opportunity to increase the quality of data collected while decreasing clinical time lines and costs. In order for the industry to continue to the extent it has, sponsors must evolve.

It was with this mindset that *Life Science Leader* magazine and NextDocs, a clinical content document management solutions provider, convened an intimate thought-leadership roundtable event in New Jersey with a goal of providing you with some best business practice information on how to improve clinical trials. In addition to myself, the participants included Mark Anderson, executive director, global head of clinical data management, Alexion; Greg Fiore, M.D., founder of SSI Strategy consultancy; Reinilde Heyrman, M.D., VP, chief clinical development officer, IKARIA; Mitch Katz, Ph.D., executive director medical research operations, Purdue Pharma; and Eva Krusinska, Ph.D., principal at PharmaLand Executive Consulting Services. Together they have a combined 125+ years of industry experience. And though you may not recognize some of their current employers, their past career experiences include more recognizable company names such as Abbott, Acorda, Amgen, Covance, Daiichi Sankyo, Eisai, Forest Laboratories, GSK, Merck, Pharmacia & Upjohn, Schering-Plough, and The Medicines Company. What follows is some good old-fashioned wisdom on how you can improve clinical trials — and it doesn't require you to spend a fortune on the latest whiz-bang gizmo or gadget.

ARE YOU ASKING THE RIGHT QUESTIONS?

One of the first questions I posed during the group discussion was fairly straightforward: How can we improve clinical trials? According to Katz, a good place to start is by reducing the complexity of clinical trials. "We have used clinical trials

to try to answer too many questions," he states. "Louis Lasagna [respected expert in clinical pharmacology] taught us that if you ask too many questions, you are going to lose the focus of your trial." Anderson agreed, adding, "If we don't get that under control, we could be asking a lot of questions that really don't gain us much information about the actual effectiveness of the drug or what could be commercialized as we go forward."

The initial thought behind asking lots of questions in a study was that it would reduce costs, because it would decrease the likelihood of having to do an additional study. Though intuitively this makes sense, it does not fit with the reality of what happens in the field. "What we see coming back from our sites is that the more data you ask for, the more involved the trial will be," says Heyrman. "This is not conducive for either patients or science, and it results in higher costs." (For an additional example of how industry practices are not always conducive to patients, see sidebar, "Cookie-Cutter Informed Consent Creates Confusion, Not Comprehension.") She advises always keeping in mind exactly what is needed for the successful registration and launch of a drug — probably in more regions of the world than just one. A simple technique taught to Heyrman by one of her mentors regarding clinical trial development was, "Ask yourself what exactly you think you're going to do with every single piece of data. If you can't answer that straightforwardly, the next question should be: 'Why exactly then are you even collecting it?'" For example, while working at a different company more than 10 years ago, Heyrman relates that one of the clinical trial procedures involved the collection of concomitant medications. "While we found out what concomitant medication was being used, we never collected the dose or administration route," she states. This changed when she went to another company that considered it heresy not to collect dose, mode of delivery, and frequency of concomitant medications, though she admits that in the absence of an adverse event, little, if any, data analysis was ever conducted.

Much of the "collect-and-monitor-everything" mantra that has existed in clinical trials was driven by the legacy of Big Pharma deep pockets. Katz believes industry is shifting toward simplifying clinical studies, and this shift is being driven by smaller companies with limited resources making smarter decisions. "Because you have one shot," he says, "you have to pick the best choices for your primary and secondary efficacy end points." That being said, during some of Krusinska's recent consultancy work she found the reverse to

Simplifying Clinical Studies Provides Spirited Debate

During our recent clinical trial thought-leadership roundtable, one thing became clear — simplifying the clinical trial process is a desirable goal. To do so, members of the roundtable suggested that we need to ask the right questions — sparking the following spirited debate.

Katz: "So we put everything but the kitchen sink into a trial, and we realize at the end of the day we've collected a lot of rubbish. It causes us a lot of discrepancy resolution problems and costs us a tremendous amount of money. You've got to get simple."

Krusinska: "You were mentioning complex designs leading to operational difficulties. It's not only operational difficulties. Actually it does not work for science, either. If I have 200 end points, what value does it bring statistically?"

Anderson: "What we need to look for from the beginning is — are we asking the right questions to start with?"

Katz: "But the questions have to be aligned with what the regulatory agencies are looking for. The reason we collect everything is because we anticipate that eventually the FDA is going to ask us a question about the data."

Heyrman: "But honestly, you can give them the answer, 'We didn't collect that. Sorry.'"

Fiore: "As long as you demonstrate that you thought about it and had good reasoning."

Anderson: "But the fear is, they're not going to approve it, and you'll have to do another study. That's the issue companies struggle with in designing studies."

Katz: "Agencies sometimes give contradictory recommendations or direction. They tell you one thing once, and then eventually, as they learn more, they'll change their minds. It became very obvious to me that these agencies need to partner with industry. The regulatory agencies may not have the bandwidth to fully understand the implications and consequences of their changing decisions."

Anderson: "We've got to change our way of thinking. It would be great for our government and other regulatory agencies around the world to say, 'We want it this way.' We are a conforming industry. If you tell us something, you'd be surprised how fast we're willing to get behind it and align to it. I have yet to see something where guidance comes out and somebody says, 'It is too difficult to comply with that guidance, so we're going to submit the information the way we've collected it.'"

Fiore: "We tolerate extreme subjectivity in the industry, and Mark [Anderson], with what you're saying, it would make sense if there were more clarity, because this subjectivity fuels the 'I need to collect more, I need to be ready for any question a regulatory authority asks for.'"

Heyrman: "It's really not the health authorities; that's just a nice smoke screen we use to protect ourselves. If my scientist cannot explain to the data manager why we need to collect this piece of data, it probably isn't worth collecting. If you can't explain to somebody not in your field why you want to have what you want to have, question yourself as to whether you really need to have it."

I have heard similar debates in other forums, with some folks advocating for specific regulatory clarity as to what is required. This is not likely going to happen — and for good reason. Though the FDA's remit is safety and efficacy, it also needs to create an environment where people feel comfortable being able to question and challenge convention in order to spark innovation. Rather than seeking greater regulatory specificity handed down from the FDA, instead, the goal should be to strive to create a greater degree of collaboration and transparency between industry and regulatory agencies. L

be true. "A client wanted to conduct a trial with six 'arms,'" she states. "They wanted to compare each 'arm' with everything. It wasn't a large pharma company with deep pockets, but a very small start-up that wanted to get everything done in one trial." According to Anderson, this propensity in smaller companies to try to collect every piece of ancillary information persists out of the fear that a regulatory agency might, at some point, ask for it. He doesn't believe this to be adequate justification for overcomplicating a trial and reminds, "If you fail to ask a question, you can always do another clinical trial." In other words, don't fall into the trap of trying to capture everything just to remain bound to the clinical trial time line. To ask better questions requires greater deliberation in the clinical trial design process at the beginning of the study design. This requires slowing down the overall process if you really want to speed up completing a well-designed study.

SPEED UP BY SLOWING DOWN

A recent study of 343 businesses, published by the *Harvard Business Review* in conjunction with the Economist Intelligence Unit, revealed that businesses embracing business-accelerating initiatives in order to gain an edge ended up with lower sales and operating profits than those pausing at key moments. Over a three-year period, firms that slowed down improved top-line performance — averaging 40 percent higher sales and 52 percent higher operating profits. Fiore advocates applying these same philosophies in the clinical trial space. "I like the point about asking questions about what is going to be done with each data element," he says. "By virtue of that conversation, it slows down the up-front design process." Fiore believes this is just the starting point and supports applying QbD principles to the clinical trial design process.

A recent article by Frederic Sax, M.D., Quintiles' global head for integrated drug development, provides a succinct framework for applying quality by design (QbD) principles to clinical trials — Plan-Do-Check-Act. The "Plan" phase requires what he calls design diligence. Heyrman believes it is this planning phase that serves as one of the biggest roadblocks

Cookie-Cutter Informed Consent Creates Confusion, Not Comprehension

By R. Wright

Modality teaching theory suggests that people have different learning styles — visual (sight), auditory (sound), or kinesthetic (touch/physical activity), and that people learn best with educational programs customized to meet their optimal style. In traditional education environments, teaching has been implemented kinesthetically from kindergarten through third grade, visually from grades four to eight, and through auditory means (i.e. lectures) from ninth grade through adulthood. This cookie-cutter approach has maintained widespread popularity despite numerous studies reporting its lack of effect.

Though most learners use some combination of the three styles, one or more is usually dominant and defines the best way for a person to learn new information. Why then do we as an industry take a cookie-cutter approach to providing potential clinical trial participants with lengthy informed consent documents, filled with legalese, and expect them to truly understand what it means? Informed consent serves as the cornerstone of human-research subject protection. Yet proof of comprehension of the documents that people just signed is not required and is rarely obtained.

Next to the oil and tobacco companies, the pharmaceutical industry is one of the largest industries employing lawyers in the world. Pharmaceutical company legal departments charged with minimizing their company's exposure have traditionally provided clinical trial informed consent documents in a one-size-fits-all format. This may satisfy lawyers, but it doesn't really satisfy anyone else, and it does little to accommodate different patient learning styles, let alone facilitate their understanding. Mitch Katz, Ph.D., executive director medical research operations, Purdue Pharma, says, "It doesn't inform the patient. It basically scares the living daylights out of them." Some advocate e-consenting as a solution. "The beauty of the e-consent is that the patient can go home, get on a website, and read it again," says Katz. "It gives you an opportunity to think about it more." However, e-consenting doesn't go far enough if it is only taking the lengthy document and putting it in an electronic format. "The biggest excitement I have had in the past five years has been my ability to now make information visual for people so they can make better and faster decisions on study data," says Mark Anderson, executive director, global head of clinical data management at Alexion. "Information can be processed quickly on a regular basis, and there is the ability to generate graphs and other visual displays with some of the new software tools that really allow people to access specific patient data and explore interesting data trends." How to get that information translated back to the patient and caregiver so they can make better decisions going forward is the next step Anderson believes will result in real breakthroughs.

> "Recent research found that interactive informed consent produced statistically significant higher test scores than the standard paper consent."

Recent research found that interactive informed consent produced statistically significant higher test scores than the standard paper consent. Using an iPad, the interactive informed consent provided subjects with multiple options for hearing, viewing, and reading material. They can take a test and then get immediate feedback. Essentially, they have the ability to complete any form at their own pace. Subjects using the iPad spent nearly 10 more minutes viewing the informed consent than those using paper (22.7 minutes with the iPad vs. 13.2 minutes with paper). Even more telling is the fact that overall satisfaction and enjoyment slightly favored the interactive iPad presentation, despite taking nearly twice as long to complete.

I recently had the opportunity to speak with an executive of a top-10 pharmaceutical company testing an e-consent system similar to that described above. One of the initial findings was that it didn't have the ability to print out the informed consent forms. When I inquired if the patient was able to take the iPad home to view the e-consent at their leisure or open up the document online via a home computer, the answer was "No," illustrating why providing the patient with a printed version was so important. As research has demonstrated a greater level of engagement by patients using an interactive format, it is not clear why we want the patient to be engaged only when they are at the clinical trial site and not when at home. When you consider how the interactive approach accommodates multiple learning styles and improves comprehension, why then are we still sending the patient home with a printed version and expecting them to be able to adequately convey the consent information to friends and family in a single, noninteractive format? Greg Fiore, M.D., founder of SSI Strategy consultancy, says informed consent can't be just patient-centric, but must be people-centric. "If you want to improve clinical trials, let's start by improving the informed consent education process so as to increase comprehension and decrease confusion," Fiore says.

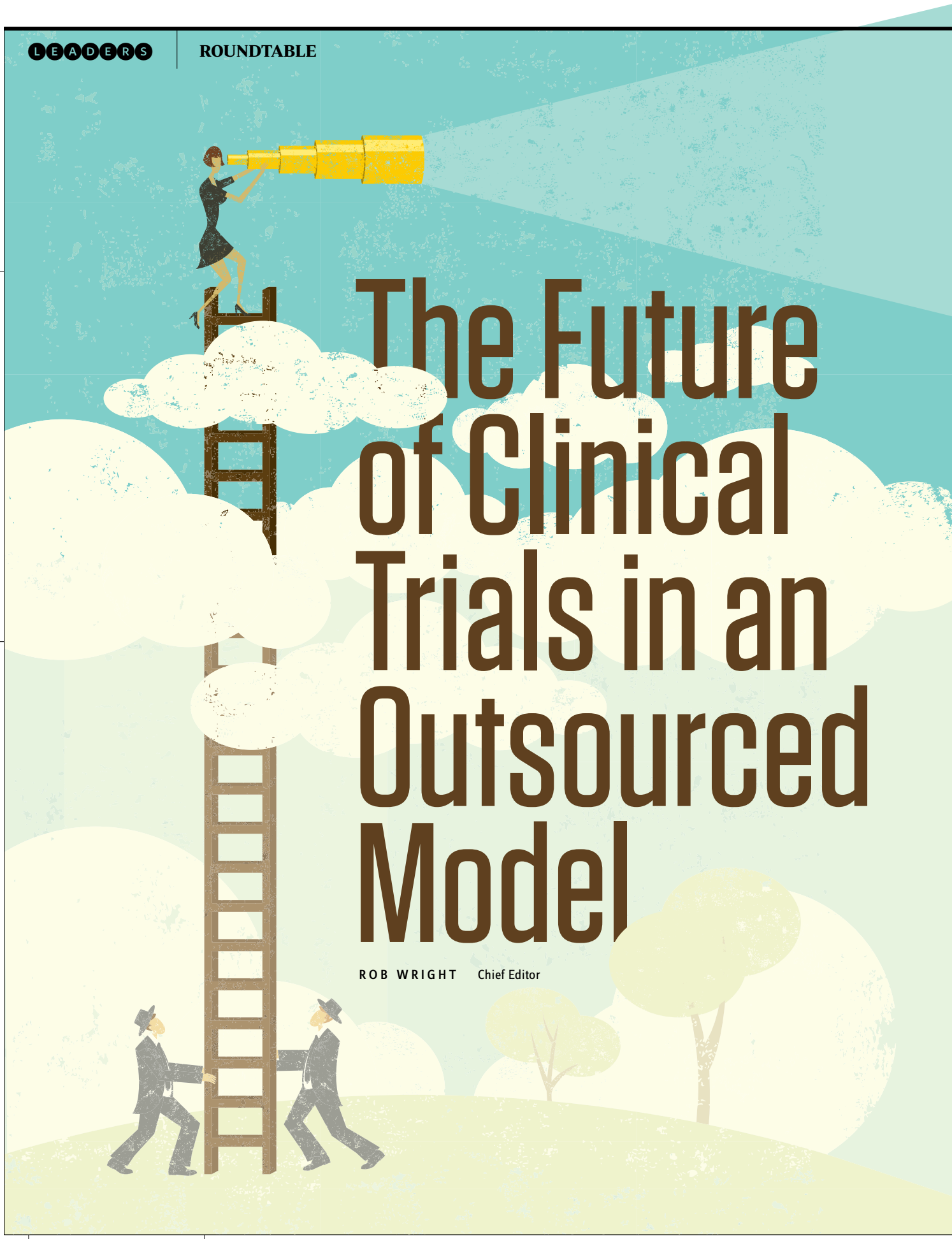
to improving clinical trials. "If you really want the trial to go quicker, it actually requires more thinking up front," she says. The challenge is the changing of the mindset, because it feels like you are starting slower. "It is so much easier to quickly design a trial. Get it all started. Then make amendments one, two, three, and so on along the way," she states. "But how much money did we allocate by making the changes?" Heyrman notes that taking this approach is usually driven by what she describes as the "all-encompassing, first-patient-in syndrome" and doesn't result in the trial being completed any faster. However, it does result in costing more. It may seem cliche, but Anderson advocates spending 90 percent of your time on the planning component of the trial and 10 percent on the execution. In the planning phase, Katz suggests gaining a greater understanding of the practice of medicine in the field when conducting global clinical trials. "On the front end, we need to involve the right people, who may or may not be key opinion leaders, but who know the practice of medicine in the relevant regions and what is really feasible when designing the study from a practical standpoint."

Anderson suggests a good place for starting the trial design is to begin with the drug label and work your way back. "I've got to make sure I have a good product package insert in order to give me a good drug label," he says. "This is going to allow me to get my product on the market. Further, a good label provides for a point of differentiation, which leads to greater commercial viability." To that end, Krusinska advises you to talk to the commercial side and get them involved early in the process. "Don't apply this approach to individual trials," she states. "You have to involve the commercial team across clinical development plans." Fiore adds, "We also need to think about reimbursement, so as to build in pharmacoeconomic elements as early as practically possible." Katz agrees. "Where we have to get a little smarter is planning for third-party payer involvement. We need to partner with them before we even start Phase 3 trials."

The consensus is that the good old-fashioned wisdom on how to improve clinical trials can be described by the word *simplify* and the following principles:

- Ask the right questions.
- Spend more time on planning so as to come up with designs that make sense.
- Gain alignment between industry and third-party payers for reimbursement purposes.
- Gain alignment between industry and regulatory agencies so you provide them with what they want (see sidebar "Simplifying Clinical Studies Provides Spirited Debate").

In the words of Katz, "We have to get back to the basics."



The Future of Clinical Trials in an Outsourced Model

ROB WRIGHT Chief Editor

Q&A

C.GALLEN, M.D., PH.D.

M.R.KELLER

J.ORLOFF, M.D.

Throughout human history people have held a fascination with trying to predict the future, employing a variety of tools — crystal balls, palm readings, tarot cards, or my personal favorite, the Magic 8 Ball. Scientists typically use data when forecasting the future.

Another common future prediction tool, and one employed by *Life Science Leader* magazine for this roundtable, is that of expert opinion. I posed 10 questions to three clinical research experts to get a sense for the future of clinical trials in an outsourced model. The experts included Christopher Gallen, M.D., Ph.D., CEO SK Biopharmaceuticals; Mary Rose Keller, former VP of clinical operations, Sangart; and John Orloff, M.D., former SVP and chief medical officer, Novartis.

Of course, there are plenty of experts who have been wildly wrong when predicting the future, such as the head of Warner Brothers who said in 1927, "Who the hell wants to hear actors talk?" Conversely, there are examples of forward-thinking experts (e.g. Warren Buffett, Jeff Bezos) who have demonstrated a mastery of anticipating the future and capitalizing on it. Travel with me now as we journey into the potential future of clinical trials in an outsourced model.

1 *Life Science Leader*: How will future clinical trials (three to five years) in an outsourced model be different from today, and why?

C. GALLEN, SK Biopharmaceuticals: Replacement of thoughtless, copy-the-last protocol, high-variance designs by expanded use of genomic, biomarker, and clinical enrichment designs (e.g. randomized withdrawal) will produce a more informed population selection. Sophisticated modeling combined with smarter Phase 2 programs will better define the dose, design, populations, and desirable outcome variables to reduce false negative trials.

M. R. KELLER, formerly of Sangart: I don't see a radical change, but I anticipate some evolution. CRO success is demonstrated in the metrics. CROs have the opportunity to influence study design and the elimination of excess secondary elements. Research from Tufts indicates sponsors are continuing to create complex protocols that are difficult to execute. CROs, as objective service providers, can help sponsors move toward more efficient and effective trial designs, and they will have the data to demonstrate the risks of poor trial design.

J. ORLOFF, formerly of Novartis: There will be full operational as well as strategic integration of CRO resources with the sponsor's global program team that will make the relationship less transactional and more cohesive. This model also will move beyond the execution of clinical trials to trial design and strategic input into clinical development plans, and it will require different skillsets and expertise on both sides compared to what commonly exists today.

2 What do you anticipate as being the biggest challenges in executing future clinical trials in an outsourced model, and why?

Most trials and most CRO expertise is focused on the U.S. and Western Europe, while the vast majority of potential patients live outside that region. In the past, this made sense with the rationale of serving the big markets. But due to economic and demographic changes, there will be a need to develop first-rate, cost-effective trial-conduct capabilities in the Asia-Pacific region and potentially North African regions.

Colleagues who work within CROs are becoming increasingly disconnected from the discipline of drug development. Previously, it was common for many CRO employees to have sponsor experience, having joined a CRO when their sponsor company had downsized. Thus, they took their development experience into the new role. But now some CROs are staffing with individuals who have no pharma, biotech, or device experience. Inexperienced field staff may miss critical information due to their lack of knowledge regarding how medical practice differs from ideal drug development plans.

The clinical trial enterprise is endangered because the model is antiquated and has not kept pace with advances in technology. Potential economic advantages of these improvements are absorbed by the legacy system. Incentives for an outsourced model must be reengineered to accommodate the need for more efficient practices in lower-cost settings, with rewards for efficiency and simplicity rather than volume and complexity.

3 How do you anticipate overcoming these challenges?

I think that basic economics will prevail. On the demand side, pharma companies are beginning to appreciate that for drugs entering development now, much of their future market will be in the Asia-Pacific region. Biotechs are lagging in this knowledge both for reasons of parochial orientation and resource limitations, and because the specialty markets they typically focus on are more developed in the West. In any case, demand will increase. Some global pharma companies are developing a presence in the region, albeit at prohibitive costs. Competition from emerging local providers will drive pricing, while more opportunity will drive local and medium-to-large CROs to seize first-mover advantage. In parallel, I think most regulatory authorities will move toward ICH (International Conference on Harmonization)-type standards.

Project leaders need to have a plan to provide exceptional training and oversight to give monitors and managers the perspective required to achieve quality study execution. Sponsors must take staff "onboarding" seriously to ensure the CRO staff is well-versed in the goals of the project and endpoints of the studies. As we begin to more heavily rely on Big Data and remote monitoring, staff need to be able to critically review data for signals that impact the conduct and reporting for the study — again the ability to put everything into the perspective of the overall development process and plan.

Fully integrated strategic partnerships between a CRO and a sponsor constructed to deliver on a program rather than á la carte transactional deliverables have the potential to reverse some of the existing incentives that undermine the goals of efficiency and simplicity. This could create a more cost-effective and flexible model that caters to the core skills of each partner.

4 In the future, what internal/external roadblocks will prevent companies from successfully executing a clinical trial in an outsourced model?

Weak signals come from narrow, super-selective, mechanistically targeted compounds whose effects are partially neutralized by compensatory processes in complex systems. Pharma companies will develop more robust multimechanistic compounds using pathophysiological screening to increase signal strength and trial power. CROs focused on time and cost but not quality generate high variance results reducing power, requiring high intellectual expertise to use computer-assisted R&D to detect high variance sites and measurements and to correct errors and quality issues in real time before trials are compromised.

Misaligned goals represent a real roadblock seldom addressed by either sponsors or CROs. Although both organizations seek quality, sponsors are primarily concerned with time and CROs with cost, resulting in a difference in focus. "Us versus them" scenarios continue to be the norm. Communication between the internal/external parties is often limited to status reports to avoid difficult com-

munications and issue resolution.

Some roadblocks include competing incentives existing within traditional models, competing trials from different sponsors in the same disease area that impede enrollment, soaring costs in Western countries, increasing trial complexity, and lack of global harmonization in clinical and regulatory requirements, including study start-up procedures.

5 How would you approach minimizing the impact of these roadblocks on the successful execution of your trials?

Regarding the internal roadblocks, the single most important consideration is strategic thoughtfulness. Specifically, there needs to be consideration of the right discovery approach to produce robust, differentiated compounds; the right selection of the initial indication most pertinent to and most likely to be responsive to a given pharmacological intervention into its pathophysiology; and use of the right trial design, power, and selection of dependent variables to detect and define the true effect of the medication on the disease. Essentially, you need to be smart about how you pick the drug to test, the disease to test it in, and the things to measure. The regulatory hurdles reflect political and sociological concerns as well as the career incentive systems of the regulators. Hence, you need to accept that these barriers exist, only undertake programs where those barriers will not be fatal to your chances of success, and work closely with the specific regulators to ameliorate the overall problem as it pertains to your therapy.

Every project must have a proper kick-off session to establish shared goals with clear roles and responsibilities agreed upon by sponsor and CRO. Frank, constructive conversations must occur between all the parties to establish the team, with members agreeing to honor the team objectives. Most start-up sessions focus on the tasks to execute, not how the team will work together. In addition, it is critical that both the sponsor and CRO agree to reward team members based on these shared objectives and goals.

Each of the roadblocks identified above requires a specific focused approach, but for many of them, the challenges will not be completely overcome until we address the bigger issue relating to the business model for conducting clinical trials. In Western countries, conducting large-scale outcomes trials has become prohibitively expensive and inefficient. Novel approaches to the clinical trial model must be tested and explored, which include moving away from traditional clinical research settings at tertiary care centers to community-based locations that are closer to the patients we have

trouble engaging in the clinical research enterprise. Combining new community-based models with disruptive technologies (eSourcing, eConsent, EMRs, Web-based approaches) has the potential to dramatically transform clinical research and put it back on a path to efficiency, success, and productivity.

6 What do you envision as being the biggest opportunities (e.g. social media) for conducting clinical trials of the future, and how should companies capitalize on these opportunities?

At this time, the percent of the population with any given disease condition participating in a clinical trial is quite low — typically around a few percent. Social media, broadly speaking, is an important and underutilized means of educating and reaching potential trial participants.

I have become a fan of crowdsourcing. As the pharma industry moves toward greater transparency, it opens the door for greater input from the full spectrum of customers (investigators, researchers, patients, advocates). Many companies are posting a protocol synopsis for general comment from interested parties, and the results have been stunning in terms of improving the study. Also, new productive investigators have been found among those who are motivated to connect and comment.

Web-based and social media approaches to identifying the right patients for clinical trials, especially in remote settings not currently accessed by traditional methods, would help to overcome recruitment woes. EMR (electronic medical record)-embedded electronic flags to providers are already being tested successfully in identifying potential trial candidates. Electronic consent is being used in some trials as a way to access new patients and facilitate their participation in clinical trials. Electronic sourcing will overcome the redundancies and inaccuracies involved in paper-based source documents, and it will enable real-time data monitoring to improve trial execution and ensure patient safety.

7 How do you think CROs of the future will differ from how they look today, and why?

Frequently the large CROs are often undifferentiated (no distinguishing features) and inconsistent (great experience one trial, terrible experience the next). The reality is that CRO excellence does not vary as much at the company level as it does at the individual project team level. At Pharmacia and Wyeth, we found that by defining a superior system, training people on that system, and being rigorous in the training and selection of project managers (and culling those project managers who cannot perform at a high level), it is possible to create a dominant organization. Turf, habit, and the buddy system are the enemies of first-rate performance.

CROs are well-positioned to capitalize on information technology requiring increased standardization. I can see the CROs moving into direct access of patient data from electronic medical records and testing systems, as long as the data exists in a uniform format globally. The CRO systems will evolve to manage massive amounts of information in validated environments. CROs are more likely to develop this capability than individual pharma companies.

CROs of the future will be operating in different business models compared to today (see above), becoming stronger strategic partners with sponsors. They will be fully integrated into team structures and will have accountability for delivering on a program with objectives and rewards similar to sponsor team members (i.e. much less transactional and much more strategic and program-oriented).

8 In your opinion, what are the key CRO attributes companies should be assessing today to successfully execute clinical trials of the future?

Number one now and for the foreseeable future is the specific team of people who will be executing your trial. Number two is the sophistication of their systems and their ability to reduce the costs of subsequent trials by not duplicating the work done on the current trial (e.g. by using standard data management elements or formats). Number three is the ability to conduct trials in the regions most pertinent to commercially important approvals, not just now, but at the time your compound is improved.

CROs must be the early adopters of emerging technology, novel approaches, and new concepts, which represents an interesting parallel. In the same way many larger pharma/biotech companies have enhanced their portfolios by acquiring small, novel discovery companies, CROs will make similar advances and innovations by acquiring small specialty or niche CROs. Sponsors should look for demonstrated expertise in adaptive design, risk-based monitoring, and codevelopment of biomarkers/diagnostics and drug products.

CROs will need to build their talent pipeline with the skillsets that support new operating models, with greater strategic and technical expertise, collaborative mindsets, and flexibility to work in diverse environments. And leadership will need to be open to alternative partnership arrangements that are tailored to the needs of their customers.

9 What tools and/or metrics have you found to be the best for effectively assessing these attributes, and why?

There is no alternative to dealing with the issues in detail. Interview the pertinent CRO staff with detailed technical questions of how they recognize and deal with problems. Also assess nonverbal factors such as emotional intelligence and drive for results. Ask about rewards for retaining key staff and what punishments are in place for losing them. Of course, you should also look for industry-standard information systems.

Successful uses of the attributes I describe are relatively easy to assess through the data. For example, adaptive design requires quick turnaround of data and the ability to make seamless enrollment adjustments without a negative impact to timelines. True risk-based monitoring yields variable-monitor resource utilization and quality improvement, which are also visible in the metrics. It's also important to assess the rate of acceptance of submissions to regulatory authorities. It is fine for a CRO to claim

expertise, but it must be proven by achieving approvals.

Many of the metrics for trial execution will remain the same (e.g. recruitment targets, enrollment by site, cost, data quality, etc.), while others will be more programmatic and strategic — metrics often used to assess an internal team's performance, such as trial outcome (primary, secondary, exploratory), timelines, efficiency, patient safety, and adherence to GCP.

11 In your experience, what lessons have you witnessed being learned the hard way in executing clinical trials in an outsourced model, and what advice would you have on ways to avoid these hard lessons?

First, various CROs are remarkably poor at costing out trials and preparing bids pertinent to your specific request. Bids for the same trial can vary dramatically between competing CROs due to a lack of understanding by the contracting people of what the RFP is actually asking. This can lead to selecting the wrong CRO based on the arbitrary nature of the bidding process. Another lesson I've witnessed includes selecting early indications based on the ultimate commercial target without actually determining the right dose and testing the hypothesis that the therapeutic actually affects the pathophysiology relevant to the disease. The key advice here is to define and review the proposal in detail, drilling down to understand real costs, and defining the development strategy in a manner that builds success into the process. One final lesson I've seen is being tricked by the "experience" of the CRO in conducting a given trial indication. It is only relevant if the experienced staff are on your team, not if they once worked for that CRO sometime in the past.

Projects change constantly. I see a distinct difference between internally resourced studies and outsourced studies in terms of how change is handled. Don't freak out over the resulting change orders; focus on managing the impact of the changes on the team, the investigators, and the patients. Change management has to be in every project leader's toolbox. Everyone knows that study amendments impact the cost and timelines, but if the quality of the study is maintained, you are still in business.

Communication issues underlie many challenges that arise in an outsourced model. Lack of timely communication or failure to listen to legitimate requests from either party can seriously undermine the relationship and introduce unnecessary delays or even compromise the outcome of the trial. Integration of the outsourced personnel into a cohesive team model, along with good up-front strategic planning, will help to mitigate many of these issues. Leadership on both sides can help by fostering a collaborative team environment.

Building Strategic Partnerships With CROs — Opportunities Exist For Businesses Of All Sizes On Both Ends Of The Deal

KATE HAMMEKE
Director of Marketing Intelligence, Nice Insight

As strategic partnerships become a greater focus for both sponsors and CROs, there are some concerns that these types of relationships will negatively impact the industry by causing a greater imbalance in an already perceived to be unbalanced playing field. These worries tend to come from, and impact, the smaller players in the market. Smaller clients of big CROs worry their projects will receive significantly less attention than the CROs' strategic partnerships. Small CROs worry there won't be a place for them in the industry, because they do not have as broad an offering and are unable to provide support across the entire development cycle.

The first concern comes in the form of long-term contracts from Big Pharma committing hundreds of millions of dollars and requiring significant labor investments on behalf of the CRO. These deals may cause alarm to midsize and emerging companies with a single study or smaller commitment. Yet, Nice Insight data continues to illustrate that CROs with a solid customer perception score from Big Pharma or Big Biotech have similarly strong scores across the other, smaller buyer groups. Having reviewed the scores for several of the well-known CRO giants involved in multiple strategic partnerships (ICON, PPD, and Quintiles), it is clear that the larger the percentage of respondents who have worked with the company, the higher the customer perception score — from emerging to midsize to big sponsor companies. Which means this concern comes more from speculation from businesses that merely know the company rather than actual client dissatisfaction.

The research also shows there is both value and need for three types of outsourcing relationships: tactical, preferred providers, and strategic partnerships. Looking at the data from respondents who work with CROs, we find projects are allocated to each type of relationship, but with some variation by company type. In light of the big contracts just mentioned, it is no surprise that Big Pharma has the lowest percentage of projects going to tactical providers at 23 percent. However, the difference goes toward preferred providers (47 percent) rather than strategic partnerships (30 percent). Big Biotechs have the most even allocation of projects, with approximately one-third of their business going to each type of relationship. Biotechs also exhibited the strongest interest in forming strategic partnerships, with 50 percent of respondents affirming interest.

Emerging and midsize companies currently allocate the smallest percentage of projects to strategic partnerships (27 percent), but revealed similar interest levels to Big Pharma in forming strategic partnerships — 43 percent are interested, as compared to 46 percent of Big Pharma. There are key advantages to emerging and midsize biopharma companies forming strategic partnerships, especially with global CROs. These businesses can quickly and easily expand expertise and grow their reach by partnering with a CRO. And since they tend to be smaller and less rigid than the industry giants, the advantages of a strategic partnership may come to fruition more quickly.

The second concern has been fueled by a handful of high-profile mergers between CROs. Consolidation is nothing new to the outsourcing landscape, but as big companies grow even bigger, will they begin to crowd smaller CROs from the market entirely? Nice Insight research suggests this is unlikely. With only one in ten sponsors agreeing with the statement, "My company's pipeline is strong," it makes sense that over half are increasing their discovery efforts, and roughly one-third of discovery phase spending is on outsourced work, which is good news for small CROs focused on discovery services.

While these fears have legitimate reasons for surfacing, it is important to recognize that a global, full-service CRO has the capability to successfully handle projects of different scales simultaneously. And that just because they are in a strategic partnership with a large pharmaceutical company, it is still within the company's best interest to perform tactical jobs to the same high standards that made the company an ideal strategic partner. Further, it should be recognized that many tactical projects do not require the same level or focus as long-term, multifaceted projects. This knowledge can put emerging and midsize companies at ease with the knowledge that their project will still receive the attention it deserves — and may be reaffirmed by checking the CRO's quality score as perceived by buyers from various categories.

Industry Leaders by Market Segment
Page 20-21

Company Profiles
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THE PHILOSOPHY OF THE AWARDS

Life Science Leader's pharmaceutical and biopharmaceutical subscribers 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 the industry-leading research conducted by Nice Insight. The awards incorporate the common filters used by pharma companies to vet CROs, with the added filter of peer feedback. This will help pharma companies focus on potential CRO partners that can handle their projects and are considered reputable in the industry.

The CRO Leadership Awards are based on industry research conducted by Nice Insight. Nice Insight offers intelligence reports to give clients a clear understanding of how their industry perceives their business, and a much more informed basis for strategic decision making. Nice Insight combines surveying thousands of industry executives with other key analyses to serve both partnering groups, and facilitate better overall outsourcing collaborations.

Unlike other industry awards, which are given based on a subjective voting or nomination process, the only votes that count toward the CRO Leadership Awards are those of the pharmaceutical and biopharmaceutical companies using CRO services.

PRESENTED BY:
Life Science Leader

RESEARCH CONDUCTED BY:
niceinsight
Marketing Intelligence by That's Nice

When Selecting Partners, Survey Respondents Ranked

QUALITY

as their Number One Priority.

ATTRIBUTES OF OUTSOURCING PARTNERS RANKED IN ORDER OF IMPORTANCE

#1 Quality #2 Reliability #3 Regulatory #4 Productivity #5 Innovation

WHAT ARE THE AWARDS?

Companies achieving top 20 percentile perception scores in the areas of Innovation, Productivity, Quality, Regulatory, and Reliability will be recognized for their achievement. These categories were defined for the research participants as follows:

REGULATORY AWARD: Business is reputable and compliant

THE CRO LEADERSHIP AWARDS 2014 Regulatory Award

EMERGING PHARMA	BIG PHARMA	BIOTECH	EMERGING BIOTECH
Acceleration Laboratory Services	Chiltern	BASi	ABC Laboratories
Algorithme Pharma	Covance Inc	Blue Sky BioServices	Huntingdon Life Sciences
Charles River	InVentiv Health Clinical	Celerion	InVentiv Health Clinical
Chiltern	MicroConstants	LabCorp Clinical Trials	Lambda Therapeutic Research
Impact Analytical	PPD	MPI Research	MPI Research
INC Research	QPS Holdings LLC	PPD	QPS Holdings LLC
Lambda Therapeutic Research	Quanticate	Quintiles	Quintiles
PAREXEL International Corporation	Ricerca	Ricerca	SCYNEXIS
Sannova Analytical	SNBL	Sannova Analytical	Surpass
Seventh Wave Laboratories	Surpass	SCYNEXIS	Tandem Labs
Surpass	Tandem Labs	SGS Life Science Services	Theorem Clinical Research
Wolfe Labs		Spaulding Clinical Research	Worldwide Clinical Trials
		WIL Research	
		Worldwide Clinical Trials	

INNOVATION AWARD: Business will enhance in-house capabilities through a new idea, method, or device

THE CRO LEADERSHIP AWARDS 2014 Innovation Award

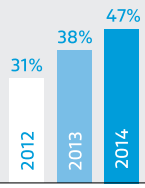
EMERGING PHARMA	BIG PHARMA	BIOTECH	EMERGING BIOTECH
Acceleration Laboratory Services	BRI (Biopharmaceutical Research Inc.)	Celerion	ABC Laboratories
Algorithme Pharma	Chiltern	ICON plc	Chiltern
APS (American Preclinical Services)	Covance Inc	Impact Analytical	CiToxLab
Eurofins Lancaster Laboratories	Eurofins Lancaster Laboratories	Lambda Therapeutic Research	MPI Research
Impact Analytical	GenScript USA Inc.	MPI Research	QPS Holdings LLC
INC Research	ICON plc	Quintiles	Quintiles
Lambda Therapeutic Research	LabCorp Clinical Trials	Ricerca	Ricerca
PAREXEL International Corporation	Lambda Therapeutic Research	Sannova Analytical	SCYNEXIS
Quanticate	MicroConstants	Spaulding Clinical Research	Spaulding Clinical Research
Sannova Analytical	PPD	WIL Research	Surpass
Smithers Avanza	QPS Holdings LLC		Theorem Clinical Research
Theorem Clinical Research	Quanticate		
Wolfe Labs	Ricerca		
	Surpass		
	Wolfe Labs		

2014 BUYING TRENDS

Annual Outsourcing Expenditure

Less than $10M
2013 to 2014: -9%
29%

$10M to 50M
2013 to 2014: +9%
47%



More than $50M
2013 to 2014: 0%
24%

Average # of Methods Used to Select an Outsourcing Partner
2.8

QUALITY AWARD: Business will treat the project as if it was their own

THE CRO LEADERSHIP AWARDS 2014 Quality Award

EMERGING PHARMA
Algorithme Pharma
American Preclinical Services
Charles River
Chiltern
Eurofins Lancaster Laboratories
Lambda Therapeutic Research
PAREXEL International Corporation
Quanticate
Seventh Wave Laboratories
Tandem Labs
Theorem Clinical Research
WIL Research

BIG PHARMA
Celerion
Covance Inc
Eurofins Lancaster Laboratories, Inc.
GenScript USA Inc.
ICON plc
MicroConstants
MPI Research
PPD
QPS Holdings LLC
Quanticate
Ricerca
SNBL
Surpass

BIOTECH
ABC Laboratories
Celerion
Covance Inc
Harlan Contract Research Services
ICON plc
Impact Analytical
MicroConstants
MPI Research
PPD
Product Safety Labs
Quintiles
RPS Strategic Solutions
Ricerca
Sannova Analytical
Smithers Avanza
Spaulding Clinical Research
WIL Research
Worldwide Clinical Trials

EMERGING BIOTECH
ABC Laboratories
Charles River
Chiltern
CiToxLab
Frontage
MPI Research
PRA
Quintiles
Ricerca
SCYNEXIS
Seventh Wave Laboratories
Surpass
Tandem Labs
Theorem Clinical Research

PRODUCTIVITY AWARD: Business will deliver on agreed objectives

THE CRO LEADERSHIP AWARDS 2014 Productivity Award

EMERGING PHARMA
Acceleration Laboratory Services
Algorithme Pharma
Charles River
Covance Inc
Eurofins Lancaster Laboratories, Inc.
Impact Analytical
Lambda Therapeutic Research
PAREXEL International Corporation
Seventh Wave Laboratories
SGS Life Science Services
Surpass
Theorem Clinical Research

BIG PHARMA
BRI (Biopharmaceutical Research Inc.)
Covance Inc
GenScript USA Inc.
LabCorp Clinical Trials
PPD
QPS Holdings LLC
Quanticate
Quintiles
SCYNEXIS
Surpass
Tandem Labs

BIOTECH
Celerion
CiToxLab
Frontage
ICON plc
Impact Analytical
MPI Research
PPD
Sannova Analytical
Spaulding Clinical Research
WIL Research
Worldwide Clinical Trials

EMERGING BIOTECH
ABC Laboratories
Chiltern
GenScript USA Inc.
MPI Research
QPS Holdings LLC
Quintiles
Ricerca
Spaulding Clinical Research
Surpass
Tandem Labs
Theorem Clinical Research

RELIABILITY AWARD: Business will meet all project milestones and timelines

THE CRO LEADERSHIP AWARDS 2014 Reliability Award

EMERGING PHARMA
Acceleration Laboratory Services
American Preclinical Services
Chiltern
Eurofins Lancaster Laboratories
INC Research
Lambda Therapeutic Research
PAREXEL International Corporation
Quanticate
Seventh Wave Laboratories
Smithers Avanza
SNBL
Surpass
Theorem Clinical Research

BIG PHARMA
Covance Inc
Eurofins Lancaster Laboratories, Inc.
GenScript USA Inc.
Lambda Therapeutic Research
PAREXEL International Corporation
PPD
QPS Holdings LLC
Quanticate
Ricerca
SNBL
Surpass
Tandem Labs
Wolfe Labs

BIOTECH
BASi
Celerion
ICON plc
Impact Analytical
LabCorp Clinical Trials
MPI Research
Quanticate
Ricerca
Sannova Analytical
SGS Life Science Services
WIL Research

EMERGING BIOTECH
ABC Laboratories
Chiltern
CiToxLab
Frontage
Huntingdon Life Sciences
InVentiv Health Clinical
QPS Holdings LLC
Quintiles
SCYNEXIS
Surpass

CATEGORIES WON:

ABC Laboratories

Columbia, MO
www.abclabs.com

+1 800 538 2227
Kristein King
kingk@abclabs.com
Key locations: Columbia, MO and University of Missouri Discovery Ridge Research Park

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, and Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

MAIN SERVICE AREAS:
Bioanalytical, Clinical, Preclinical, CMC Analytical

SERVICES & CAPABILITIES: Comprehensive analytical support for large and small molecules, preformulation through commercial release: MD/MV; development & commercial stability; extractables & leachables; release testing; metabolite/impurity isolation, ID and characterization; bioanalysis; DMPK; plus niche expertise in radiolabeling synthesis and environmental assessments

THERAPEUTIC AREAS: All therapeutic areas, including those involving high-potency and cytotoxic drugs.

JOHN BUCKSATH
president and CEO

"It is an honor to be recognized for the 2014 CRO Leadership Award by our clients. It is validating to see our investments in expertise, talent, and leadership, combined with a strong foundation in quality, service, and capacity, are coming together. Our mission is to be a trusted extension of our client's development team."

CATEGORIES WON

Acceleration Laboratory Services, Inc

Lee's Summit, MO
http://accelerationkc.com/

+1 816 525 1150
Rob Poe
rpoe@accelerationkc.com
Key locations: Greater Kansas City, MO

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

MAIN SERVICE AREAS:
Clinical, Preclinical

SERVICES & CAPABILITIES: Acceleration provides support for clinical trials in method development and validation of methods for analysis and release of clinical dosage formulations. Preclinical support is provided in characterization and production of API, formulation support, and tox dose analysis.

THERAPEUTIC AREAS: Acceleration supports all therapeutic areas, yet has extensive experience in working with oncolytics, cytoxics, and other highly potent compounds.

BRENT TAYLOR
CEO

"We are, once again, honored to be thought of so highly by our peers within the life sciences industry, through the CRO Leadership Awards. Earning awards within the categories of reliability, innovation, productivity, and regulatory is a testament to the dedication and passion of each member of the Acceleration team. Our experienced team strives to find the most efficient solutions for our clients, and to not simply focus on the finish line, yet to ensure the path we take is one that will allow long-term success."

CATEGORIES WON

Algorithme Pharma

Laval (Montreal), Quebec, Canada
www.algopharm.com

+1 450 973 6077
Catherine Konidas, VP Global Business Dev.
ckonidas@algopharm.com

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

MAIN SERVICE AREAS:
Clinical, Bioanalytical

SERVICES & CAPABILITIES: Algorithme Pharma provides a unique, full-service offering focused on early stage clinical development. Our services include the design and conduct of Phase I/IIa clinical trials, large and small molecule bioanalysis, data management, biostatistics, regulatory support, clinical pharmacology, and project management.

THERAPEUTIC AREAS: Algorithme Pharma provides research services to the pharmaceutical, generic, and biotechnology industries, with particular expertise in metabolic disease, nephrology, inflammation, hormone therapy, and infectious disease.

CHRIS PERKIN
chief executive officer

"Partnering with our clients to get their drug through this critical early stage of drug development is our company focus. It is very rewarding to have these efforts recognized, as we work hard to treat every project with individualized attention, and to provide a personalized and customized service that surpasses our clients' expectations. Our company is continuously looking for ways to improve our customer relationships and our range of services to create even greater value for our sponsors."

CATEGORIES WON

American Preclinical Services

Minneapolis, MN
www.americanpreclinical.com

+1 763 717 7990
Michael Conforti
mconforti@apsemail.com
Key locations: Minneapolis, MN

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical

MAIN SERVICE AREAS:
Preclinical

SERVICES & CAPABILITIES: Interventional and surgical research; biocompatibility research; toxicology and pharmacology; pathology services; human cadaver labs; physician training, and simulation labs

THERAPEUTIC AREAS: Have worked in all therapeutic areas.

"Innovation, Quality, and Reliability – We Can Do That! At American Preclinical Services (APS), we have built and we will continue to build an organization around the adage 'We Can Do That'. With a wide breadth of staff expertise and expansive bricks-and-mortar laboratory space - APS has the foundation to continually meet our sponsor's high productivity and reliability requirements."

CATEGORIES WON

BASi

West Lafayette, IN
www.BASinc.com

+1 765 463 4527
Frances Leath
fleath@BASinc.com
Key locations: West Lafayette, IN and Mount Vernon, IN

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

MAIN SERVICE AREAS:
Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Culex® *In Vivo* Drug Discovery (ADME, neuroscience), preclinical toxicology (GLP/non-GLP), bioanalytical (method development, validation, and sample analysis), and pharmaceutical analysis (*in vitro* bioequivalence, electrochemical detection, dose formulation analysis)

THERAPEUTIC AREAS: Diabetes, infectious disease, biomarkers, pain, cardiology, gastrointestinal, neurology/CNS, oncology, steroids, drug-coated medical devices

JACQUELINE M. LEMKE
president and CEO

"We are pleased to be recognized as leaders in our industry for our regulatory compliance and reliability. Our clients expect this level of excellence, and we are happy to deliver it. This year we celebrate our 40th anniversary and look forward to continued success with our partners in pharma, biotech, and the regulatory agencies. Regulatory excellence, along with innovation and customer service, are our top priorities."

CATEGORIES WON

Blue Sky BioServices

Worcester, MA
www.blueskybioservices.com

+1 508 749 3226
Scott Gridley
sgridley@blueskybiotech.com
Key locations: Worcester, MA

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical

MAIN SERVICE AREAS:
Preclinical

SERVICES & CAPABILITIES: Gene synthesis, plasmid production, gene to antibody, E. coli expression and scale-up, insect expression and scale-up, mammalian expression and scale-up, antibody cloning, antibody production, protein purification, radiometric assays, assay development, and screening

TED MARPLE
president and chief executive officer

"Blue Sky is dedicated to meeting our clients' needs by focusing on quality, speed, and scientific expertise. Our state-of-the-art labs and experienced scientific team enable us to consistently deliver excellent service and quality, on time for our clients. This recognition of our commitment to great science and customer service is derived from leading pharmaceutical and biotech companies across the world who have confidence and trust in Blue Sky and our commitment to partnerships with them."

CATEGORIES WON:

Celerion

Lincoln, NE
www.celerion.com

+1 402 476 2811
David Maya, VP Business Development
david.maya@celerion.com
Key locations: Belfast, Northern Ireland, U.K.; Lincoln, NE; Neptune, NJ; Phoenix, AZ; West Conshohocken, PA, U.S.A; Montreal, Quebec, Canada; Zurich, Switzerland

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

MAIN SERVICE AREAS:
Bioanalytical, Clinical

SERVICES & CAPABILITIES: Celerion conducts first-in-human, clinical proof-of-concept, cardiac safety, and NDA-enabling clinical pharmacology studies. Support is also provided in statistics, and PK/PD analysis, small/large molecule bioanalytical services, as well as program management.

THERAPEUTIC AREAS: Provide support in metabolic diseases, respiratory, inflammation, cardiovascular, hypertension, ophthalmology, and infectious diseases.

SUSAN THORNTON, PH.D.
president and CEO

"Celerion, a leader in early clinical research, delivers applied translational medicine through the implementation of innovative strategies to generate key data very early and enable faster go/no-go decisions in drug development. For more than 40 years our experienced people, scientific and operational excellence, combined with our innovative approach, have enabled us to deliver high-quality data while reducing timelines and cost for our clients. It is an honor to have our clients recognize us with these awards."

CATEGORIES WON

Charles River

Wilmington, MA
www.criver.com

+1 781 222 6000 or +1 877 CRiver1
askcharlesriver@crl.com
Key locations: Canada, France, Germany, Ireland, Italy, Japan, United Kingdom, United States

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

MAIN SERVICE AREAS:
Bioanalytical, Preclinical

SERVICES & CAPABILITIES: Discovery research services, research models and services, safety assessment, laboratory and pathology support, agrochemical and animal health product development, biologics testing solutions, and endotoxin and microbial detection

THERAPEUTIC AREAS: Cardiovascular, endocrine/metabolic, oncology, skeletal disease, central nervous system, inflammation, ophthalmology, vaccines/cell therapy/biosimilars

JAMES C. FOSTER
chairman, president, and chief executive officer

"We believe that one size does not fit all, and that a deep understanding of our clients is pivotal to a successful working relationship. At Charles River, we provide our clients with a flexible research platform best suited for their needs, which is integral to enhancing the research and development process. We are pleased that our clients recognize Charles River's industry leadership with this award."

CATEGORIES WON

Chiltern

Slough, UK
www.chiltern.com

+44 1753 512 000
Stuart McGuire
stuart.mcguire@chiltern.com
Key locations: Asia Pacific, Eastern Europe, Latin America, North America, Western Europe

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

MAIN SERVICE AREAS:
Clinical

SERVICES & CAPABILITIES: Chiltern is a full-service global contract research organization offering services in: early phase, global clinical development, late phase, biometrics, medical & regulatory affairs, functional service provision, and contract staffing.

THERAPEUTIC AREAS: CNS, infectious diseases & vaccines, oncology, ophthalmology, pediatrics, cardiorespiratory

JIM ESINHART
CEO

"Chiltern is honored to be recognized three years running by distinguished members of the biopharmaceutical industry as a CRO leader in quality, reliability, innovation, productivity, and regulatory. Chiltern prides itself as a global, mid-tier development partner that offers flexibility, responsiveness, and quality delivery. On behalf of our Chiltern colleagues working around the world, it is a pleasure to accept this award."

COVANCE

CATEGORIES WON

Covance Inc

Princeton, NJ
www.covance.com

+1 609 452 4440
Nigel Brown
nigel.brown@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)
Drug Substance Production: Primary Process Development, Drug Substance Production

MAIN SERVICE AREAS:
Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Pharmacology, bioanalysis and biopharmaceutical CMC (small and large molecule), ADME, nonclinical safety assessment, program management, clinical pharmacology and Phase I/IIa trials, early clinical studies, proof-of-concept studies, Phase IIb/III studies, risk-based monitoring, post-registration and Phase IV studies.

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

JOE HERRING
chairman and
chief executive officer

"Covance's commitment to science and its promise of a healthier world drives us to deliver real solutions to our clients. Our teams of talented professionals and innovative and integrated processes produce high-quality data on time or early, and on budget or below – helping our clients get their new medicines to patients sooner."

eurofins | Lancaster Laboratories

CATEGORIES WON

Eurofins Lancaster Laboratories, Inc.

Lancaster, PA
www.EurofinsLancasterLabs.com

+1 717 656 2300
Michael McDowell, Vice President Business Development and Project Management
pha@lancasterlabs.com
Key locations: Clogherane, Dungarvan Co. Waterford, Ireland; Lancaster, PA; Portage, MI

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

MAIN SERVICE AREAS:
Clinical, Preclinical

SERVICES & CAPABILITIES: Method development/optimization, validation/qualification/transfer, product release testing, stability storage & testing, raw materials testing, impurities & residuals testing, characterization, cell banking, cell line characterization, viral clearance, bioassays, professional scientific staffing℠

THERAPEUTIC AREAS: As a testing laboratory, we support all therapeutic areas of large and small molecule products. Most importantly, we have expertise in various modalities, including synthetic small molecule pharmaceuticals, as well as cell and gene therapy, synthetic peptides, therapeutic proteins, conjugates, therapeutic enzymes, and vaccines.

DR. TIMOTHY OOSTDYK
president

"It is an honor to receive the CRO Leadership Award for quality, reliability, innovation, and productivity expertise again this year. At Eurofins Lancaster Laboratories, we work extremely hard every day to deliver the most comprehensive, reliable, and timely GMP testing available for large and small molecule products. We are delighted that the bio/pharmaceutical industry continues to recognize Eurofins Lancaster Laboratories as a leader in these key areas."

FRONTAGE

CATEGORIES WON

Frontage

Exton, PA
www.frontagelab.com

+1 610 232 0100
Azhar Kalim
akalim@frontagelab.com
Key locations: Beijing, Changchun, Nanjing, Shanghai, and Zhengzhou, China; Exton, PA, Hackensack, NJ, United States

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

MAIN SERVICE AREAS:
Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Offerings include bioanalysis, preclinical DMPK, clinical and bioequivalence studies, API and product development with analytical support-spanning discovery through late-stage clinical trials. Frontage helps a diverse range of clients with data to support NDA, ANDA, and 505.b.2 submissions.

THERAPEUTIC AREAS: Frontage supports multiple therapeutic areas across different business areas, with expanded expertise in pain management, oncology, and dermatology for small and large molecules.

SONG LI, PH.D.
chairman and CEO

"We are delighted and honored to be recognized by Life Science Leader. More than anything, this recognition is a direct reflection of both our company ethos, and our talented scientists, who bring deep experience, commitment, and scientific curiosity to every project. I believe this combination of qualities reinforces a company-wide ability to solve technical problems and help our clients consistently manage complexity in drug development."

GenScript
Make Research Easy

CATEGORIES WON:

GenScript USA Inc.

Piscataway, NJ
www.genscript.com

+1 732 885 9188
Dr. Jeffrey Hung
Jeffrey.hung@genscript.com
Key locations: Amsterdam, Netherlands; Nanjing, China; Piscataway, NJ, U.S.A.; Tokyo, Japan

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical

MAIN SERVICE AREAS:
Bioanalytical, Preclinical

SERVICES & CAPABILITIES: Gene synthesis, peptide synthesis, protein services, antibody services, in vitro pharmacology, in vivo pharmacology, antibody drug development and antibody engineering, cell line services

THERAPEUTIC AREAS: Cancer, cardiovascular diseases, CNS diseases, metabolic diseases, inflammation and immune diseases, infectious diseases

FRANK ZHANG, PH.D.
CEO

"GenScript's team members are the reason for our success. We have professional teams for all aspects of customer interaction including R&D, sales and marketing, project management, and customer service. Each of our team members has the knowledge and passion to serve the life sciences and biomedical research community. The fact that our customers voted us as the best for quality, productivity, innovation, and reliability among all service providers speaks volumes about the fruitful outcome of our efforts, and reinforces our commitment to continuing to build a world-class team of employees that meets and exceeds our customers' expectations."

harlan®
Contract Research Services

CATEGORIES WON

Harlan Contract Research Services

Indianapolis, IN
www.harlan.com/crs

+41 (0)61 975 11 11
Rob Cestone
rcestone@harlan.com
Key locations: Germany, Spain, Switzerland, United Kingdom, United States

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical

MAIN SERVICE AREAS:
Preclinical

SERVICES & CAPABILITIES: Harlan Contract Research Services (CRS), a division of Harlan Laboratories, Inc., is a privately held provider of general and specialty toxicology services to the global chemical, agrochemical, and pharmaceutical industries. With laboratory locations in Germany, Spain, Switzerland, and the UK, Harlan CRS' focus is on providing customers with services to optimize product development.

MANUELA LEONE
president

"Quality remains at the heart of all Harlan CRS services as a part of our commitment to being a stable, reliable, and trustworthy partner to every client."

Huntingdon Life Sciences
Working for a better future

CATEGORIES WON

Huntingdon Life Sciences

East Millstone, NJ
www.Huntingdon.com

+1 732 873 2550
sales@princeton.huntingdon.com
Key locations: Cambridgeshire and Suffolk, U.K.

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical

MAIN SERVICE AREAS:
Bioanalytical, Preclinical

SERVICES & CAPABILITIES: Toxicology acute through carcinogenicity via standard and specialist routes, DART, safety pharmacology, genetic tox, DMPK, bioanalysis, immunoassay, cell-based assays, flow cytometry, CMC, small and large molecule, environmental risk assessment

BRIAN CASS
managing director & chief operating officer

"One of the world's largest nonclinical CROs, HLS has a 60-year reputation for attracting and training the very best scientific and technical staff to consistently deliver a high-value service for our customers. We pride ourselves on a collaborative, flexible approach, making us the premium drug development partner for many of the world's largest pharmaceutical companies, and hundreds of new and emerging companies. We're very proud our success has been recognized with these awards."

CATEGORIES WON

ICON plc

Dublin, Ireland
www.iconplc.com

+353 1 2912000
Paul Colombo
info@iconplc.com
Key locations: Beijing, China; Chennai, India; Dublin, Ireland; Frankfurt, Germany; London, U.K.; Nashville & Philadelphia, U.S.A.; Tokyo, Japan

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

MAIN SERVICE AREAS:
Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Clinical pharmacology, bioanalytical labs, clinical pathology, protocol design, biomarkers, pharmacodynamic/pharmacokinetic analysis, data management, medical and safety services, biostatistics, interactive technologies, patient recruitment, medical imaging, central laboratory services, medical writing, resourcing, health economics & outcomes research, pricing & market access

THERAPEUTIC AREAS: Cardiology/vascular diseases, endocrinology, gastroenterology, genetic disease, hematology, hepatology (liver, pancreatic, gall bladder), immunology, infections and infectious diseases, musculoskeletal, nephrology, neurology, oncology, ophthalmology, orthopedics, pharmacology, psychiatry/psychology, pulmonary/respiratory diseases, rheumatology, urology, vaccines

TOM O'LEARY
chief information officer

"We are delighted to be recognized by the industry for reliability and innovation. To us, innovation is not an option – it is a priority if we are to continue to help our customers achieve greater levels of efficiency and performance in clinical study delivery. This relentless pursuit of improvement is what distinguishes ICON as a trusted and reliable partner for our customers. We remain committed to driving innovation through leveraging the creativity, experience, and passion of ICON employees."

CATEGORIES WON

Impact Analytical

Midland, MI
www.impactanalytical.com

+1 855 427 6583
Eric J. Hill
hill@impactanalytical.com
Key locations: Midland, MI

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

MAIN SERVICE AREAS:
Clinical, Preclinical

SERVICES & CAPABILITIES: Methods development and validation, stability, extractables/leachables, release testing, R&D support, problem solving, impurities, unknown identification, heavy metals, stability indicating methods, residual solvents, USP and EU compendial testing

ERIC J. HILL
president

"Impact Analytical is proud to receive the CRO Leadership Award for Quality in 2014 from Life Science Leader. This award is recognition of the dedication our team has to providing quality results to our customers. We have a comprehensive quality program that prioritizes training, process optimization & adherence, documentation, and transparency. Our team's dedication to the customer and buy-in of our quality program are why we continuously are rated high for quality by our clients."

CATEGORIES WON

INC Research

Raleigh, NC
www.incresearch.com

+1 919 876 9300
Neil Ferguson
neil.ferguson@incresearch.com
Key locations: Australia, Canada, China, Germany, Mexico, South Africa, U.K., U.S.A.

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

MAIN SERVICE AREAS:
Clinical

SERVICES & CAPABILITIES: Alliance partnerships, biometrics, clinical data management, contracts/functional services, drug safety, functional service provider partnerships, medical monitoring, medical writing, patient recruitment/retention, project management, quality assurance, regulatory affairs, strategic consulting, study monitoring

THERAPEUTIC AREAS: Cardiovascular, central nervous system (CNS), endocrinology, gastroenterology, immunology, infectious diseases, oncology, pediatrics, respiratory, women's health.

JAMIE MACDONALD
CEO

"The CRO Leadership Awards are a symbol of recognition and respect in our industry, and we are delighted to be acknowledged again this year. We continue to focus on ensuring reliability through our metrics-driven approach, developing regulatory strategies that accelerate product progression, and on delivering innovative solutions that help our customers bring drugs to market more efficiently and effectively. To be recognized once again as an industry leader validates this commitment, and serves as a tangible symbol of our connections with customers."

inVentiv Health Clinical

CATEGORIES WON:

Princeton, NJ
www.inventivhealthclinical.com

+1 609 951 6800
Greg Skalicky, EVP Business Development
Gregory.Skalicky@inventivhealth.com
Key locations: Ann Arbor, MI; Buenos Aires, Argentina; Maidenhead, U.K.; Princeton, NJ; Quebec City, Quebec, Canada; Singapore; Zurich, Switzerland

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3, Phase 4)

MAIN SERVICE AREAS:
Bioanalytical, Clinical

SERVICES & CAPABILITIES: inVentiv Health Clinical is a leading provider of global drug development services to pharmaceutical, biotechnology, generic drug, and medical device companies, offering therapeutically specialized capabilities for Phase I-IV clinical development, bioanalytical services, and strategic resourcing from a single clinical professional to an entire functional team.

THERAPEUTIC AREAS: inVentiv Health Clinical has expertise in virtually all therapeutic areas, including CNS, cardiovascular, dermatology, endocrinology and metabolics, immunology, infectious diseases, nephrology, oncology, pain and inflammatory disease.

RAY HILL
president

"inVentiv Health Clinical is a top-tier global CRO with a unique perspective. As part of inVentiv Health, we offer a comprehensive range of integrated clinical, commercial, and consulting services that can move a promising product from clinical development through commercialization. At our core, we are a company of extremely talented and experienced individuals with much to offer – and we are appreciative of our clients' recognition for this year's CRO Leadership Awards."

LabCorp Clinical Trials

CATEGORIES WON

Cranford, NJ
www.labcorp.com/clinicaltrials

+1 877 788 8861
Josh Goldsmith, Ph.D.
ClinTrialsSales@labcorp.com
Key locations: Beijing, China; Brentwood, TN; Cranford, NJ; Durham, NC; Hollywood, FL; Los Angeles, CA; U.S.A.; Mechelen, Belgium; Singapore

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

MAIN SERVICE AREAS:
Bioanalytical, Clinical

SERVICES & CAPABILITIES: Bioanalytical testing, biomarkers, biorepository services, companion diagnostics, cytogenetics, early phase and regional capabilities, endocrinology, flow cytometry, infectious disease and viral genotyping, in vitro diagnostic device clinical trials, method development and validation in addition to global central safety testing for all your protocols.

THERAPEUTIC AREAS: LabCorp Clinical Trials provides full-service laboratory testing at wholly-owned central labs in Belgium, China, Singapore, and the U.S., including Phase I-IV trials, esoteric testing, biomarker development, and companion diagnostics.

STEVE ANDERSON, PH.D.
SVP and global head of clinical trials

"LabCorp Clinical Trials is honored to receive this special recognition from our clients in the four categories of reliability, innovation, productivity, and regulatory. This distinction spotlights our dedicated employees who make a difference for our clients each and every day. Our organization is committed to providing exemplary quality in every aspect of our business. We focus not only on the service we provide today, but also on the new and innovative solutions we will provide tomorrow. We appreciate your trust and will work tirelessly to keep it."

MicroConstants

CATEGORIES WON

San Diego, CA
www.microconstants.com

+1 858 652 4600
Ron Shevock
bd@microconstants.com
Key locations: Beijing, China and San Diego, CA

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

MAIN SERVICE AREAS:
Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Regulated bioanalysis (method development, GLP validation, and sample analysis for small molecules, macromolecules, and biomarkers), DMPK assays, metabolic stability, metabolite profiling & identification, CYP/UGT induction, inhibition & identification, pharmacokinetic analysis

THERAPEUTIC AREAS: Provide regulated bioanalysis, drug metabolism, and pharmacokinetic analysis services for all therapeutic areas

GILBERT N. LAM, PH.D.
president

"For more than 15 years, MicroConstants has aimed to function as an extension of our sponsors' development teams. Constant communication and active participation in our sponsors' programs has enabled us to suggest critical solutions to their analytical challenges, and anticipate their needs. We are so honored that our sponsors have acknowledged our efforts, and awarded us with high marks in the regulatory, quality, and innovation categories."

MPI RESEARCH

CATEGORIES WON

MPI Research

Mattawan, MI
www.mpiresearch.com

+1 269 668 3336
mpiresearch@mpiresearch.com

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

MAIN SERVICE AREAS:
Bioanalytical, Preclinical

SERVICES & CAPABILITIES: Comprehensive safety and efficacy drug development (small and large molecule) and medical device research, from discovery and preclinical through early clinical; environmental, food safety, and chemical testing; world-renowned anatomical/clinical pathology

THERAPEUTIC AREAS: Metabolic disease, cardiovascular, orthopedic, renal, neurosciences, inflammation, infectious disease, oncology, ophthalmology

WILLIAM U. PARFET
chairman and CEO

"MPI Research is honored to be recognized as an industry leader in multiple areas. This distinction represents the voice of our sponsors and is a testament to the knowledge and experience of our scientific team. Each and every employee strives to not only meet – but also to exceed – the expectations of our sponsors as we work together in providing healthcare solutions. We are pleased that, with these awards, our sponsors recognize our commitment to them."

PAREXEL

CATEGORIES WON

PAREXEL International Corporation

Waltham, MA
www.parexel.com

+1 781 487 9900
Diana Martin
Diana.martin@parexel.com
Key locations: Africa, Asia Pacific, China, Europe, Middle East, South America, United States

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

MAIN SERVICE AREAS:
Clinical

SERVICES & CAPABILITIES: PAREXEL offers worldwide regulatory expertise, Phase I-IV clinical research services, eClinical technologies that accelerate development, and integrated commercialization services. The company delivers best-practice outsourcing models focused on significant value creation.

THERAPEUTIC AREAS: PAREXEL has expertise across a broad range of therapeutic areas including oncology, cardiology, neurology, metabolism/endocrine, and infectious disease.

JOSEF VON RICKENBACH
chairman and CEO

"The drug development process is a journey with many challenges, and PAREXEL has evolved to meet these complex changes and help bring these important new drugs to market, efficiently and reliably. Navigating regulatory constraints, patient recruitment challenges, data collection, and payer demands is increasingly complex. PAREXEL's goal is to help biopharmaceutical companies create and build the shortest journey from science to new treatments."

PPD

CATEGORIES WON

PPD

Wilmington, NC
www.ppdi.com

+1 910 251 0081
ppdinfo@ppdi.com
Key locations: Austin, TX; Research Triangle Park, NC; Richmond, VA; Wilmington, NC; China, Russia, Singapore, United Kingdom

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

MAIN SERVICE AREAS:
Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Preclinical: discovery (BioDuro and X-Chem), nonclinical; Clinical: Phase I, Phase II-IIIb and post-approval; therapeutic and specialty expertise; clinical data management/IT; consulting; Laboratory Services – bioanalytical labs; cGMP labs; central labs; vaccines and biologics

THERAPEUTIC AREAS: Cardiovascular, critical care, dental pain research, dermatology, endocrine and metabolic, gastroenterology, hematology and oncology, immunology, infectious diseases, neuroscience, ophthalmology, respiratory, urology

WILLIAM SHARBAUGH
chief operating officer

"PPD's innovative solutions bend the cost and time curve of drug discovery and development to create value for biopharmaceutical clients, resulting in the delivery of life-changing therapies in a faster, more cost-effective manner. Our clients benefit from PPD's world-class scientific expertise, innovative technology, flexible service models, and operational efficiencies at every stage of the drug discovery and development continuum. We recognize that developing, engaging, and empowering our employees are keys to successful performance for our clients. Our people truly make the difference."

CATEGORIES WON:

PRA

Raleigh, NC
www.praintl.com

+1 919 786 8200
Roger Boutin
BoutinRoger@PRAIntl.com
Key locations: Buenos Aires, Argentina; Johannesburg, South Africa; Mannheim, Germany; Moscow, Russian Federation; Raleigh, NC; Singapore; Victoria, British Columbia, Canada; Zuidlaren/Assen/Groningen, The Netherlands

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

MAIN SERVICE AREAS:
Bioanalytical, Clinical

SERVICES & CAPABILITIES: PRA provides comprehensive clinical trial and strategic/embedded staffing services across all phases. We also offer integrated bioanalytical laboratories, on-site pharmacies, and clinical facilities in both Europe and North America.

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

COLIN SHANNON
President and CEO

"Quality is the single most important element in PRA. Quality is deeply ingrained in every PRA process and every system. It is our devoted PRA colleagues that drive quality throughout the company as we continuously challenge ourselves to improve and innovate. PRA is dedicated to work in close partnership with emerging biotech companies to successfully bring powerful new lifesaving medicines and devices to the patients who need them."

CATEGORIES WON

QPS Holdings, LLC

Newark, DE
www.qps.com

+1 302 369 5601
Livia Legg, VP and Head of Global Business Dev.
livia.legg@qps.com
Key locations: Delaware, Florida, Missouri, North Carolina, U.S.A.; Graz, Austria; Groningen, The Netherlands; Hyderabad, India; Taipei, Taiwan

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

MAIN SERVICE AREAS:
Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Bioanalytical: small molecules, peptides, large molecules, antibody drug conjugates, oligonucleotides, elements & elemental tags, biomarkers; Clinical: study design & protocol writing, clinical conduct, clinical project management, site management & monitoring, data management, biostatistics, CDISC-compliant clinical study reports; Preclinical: IND program management, ADME, neuropharmacology, general toxicology, reproductive toxicology

THERAPEUTIC AREAS: CNS disorders/neurodegenerative diseases, asthma/COPD, immunology/autoimmune disease/rheumatoid arthritis, inflammatory diseases/immune status/cell response, infectious disease, dermatology, oncology, allergy, anemia, bone disease/metabolism, cardiovascular disease, diabetes/obesity/lipid metabolism/carbohydrate metabolism, female healthcare/gynecological, endocrinology/reproductive endocrinology, gastrointestinal disorders, hemostasis

DR. BEN CHIEN
CEO

"I am pleased and proud of QPS employees for consistently delivering the highest grade of discovery, preclinical, and clinical drug development services. Their exceptional performance and dedication are underscored by this CRO Leadership Award. Through continual enhancements in our capacities and resources, we stand tall in our commitment to deliver superior science, quality, skilled performance, and trusted service to our valued customers. We are well-positioned to succeed in realizing our corporate vision: to become a global leader in contract research."

CATEGORIES WON

Quanticate

Hitchin, Hertfordshire, U.K.
www.quanticate.com

+44 (0)1462 440084
Daniel Chapple
Daniel.Chapple@quanticate.com
Key locations: India, South Africa, Poland, United Kingdom, and United States

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

MAIN SERVICE AREAS:
Clinical

SERVICES & CAPABILITIES: Global Clinical Research Organization (CRO) primarily focused on the management, analysis, and reporting of data from clinical trials and post-marketing surveillance. Core services include clinical data management, biostatistics, programming, medical writing, pharmacovigilance and consultancy.

THERAPEUTIC AREAS: Experience across all therapeutic areas

DAVID UNDERWOOD
President and CEO

"We are excited to hear that Quanticate has been recognized for quality, reliability, regulatory, productivity, and innovation. Our customers are consistently telling us that we are leading the industry in terms of our focus on quality and timeliness. Our current position as a leading global data-focused CRO is testament to the quality and reliability of our teams, who are able to utilize innovative solutions, such as our QuantiCliQ data visualization solution, to enable us to excel."

QUINTILES

CATEGORIES WON

Quintiles

Durham, NC
www.quintiles.com

+1 866 267 4479
Key locations: United Kingdom and United States

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

MAIN SERVICE AREAS:
Bioanalytical, Clinical

SERVICES & CAPABILITIES: Quintiles is the world's largest provider of biopharmaceutical development and commercial outsourcing services, with 28,000+ employees conducting business in approximately 100 countries. We have helped develop or commercialize all of the top-50 best-selling drugs on the market.

THERAPEUTIC AREAS: Cardiovascular, central nervous system, diabetes & endocrinology, immunology, infectious diseases, internal medicine, oncology, translational oncology, pediatrics, public health, and vaccines

PAULA BROWN STAFFORD
President,
Clinical Development

"We are so proud to have been selected in all five categories of regulatory, reliability, productivity, quality, and innovation for the 2014 Life Science Leader magazine's Leadership Award. It is a testament to the commitment of our professionals, who are dedicated to anticipating and exceeding our customers' needs. At Quintiles we are focused on transforming the delivery of clinical research, and we are leading the industry to improve our customers' probability of success."

RPS Strategic Solutions

CATEGORIES WON

RPS Strategic Solutions, A Division of PRA

Fort Washington, PA
www.rpsweb.com

+1 215 540 0700
Maria DiPietro
mdipietro@rpsweb.com
Key locations: Asia Pacific, EMEA, The Americas

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

MAIN SERVICE AREAS:
Clinical

SERVICES & CAPABILITIES: RPS Strategic Solutions delivers customized clinical development services utilizing embedded strategies designed to manage large and midsize biopharmaceutical companies' pipeline portfolios more efficiently and with greater flexibility and control.

THERAPEUTIC AREAS: Cardiovascular, CNS, endocrinology and metabolism, dermatology, gastroenterology, hematology, immunology, infectious diseases, oncology, pulmonary medicine, rheumatology, urology, and women's health

HARRIS KOFFER, PHARM.D.
President

"RPS is honored to be recognized as a leader in providing the highest quality services in support of our partners' product development portfolios. Our talented team of highly experienced professionals has a passion for customer service and quality, and unwavering commitment to helping our partners bring innovative, life-changing therapeutics to patients in need. Our innovative approach has enabled RPS to partner with our clients to transform product development, creating a more efficient and sustainable model."

SCYNEXIS

CATEGORIES WON

SCYNEXIS

Durham, NC
www.scynexis.com

+1 919 544 8600
Clare Murray
clare.murray@scynexis.com
Key locations: Durham, NC

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical
Drug Substance Production: Primary Process Development, Drug Substance Production

MAIN SERVICE AREAS:
Preclinical

SERVICES & CAPABILITIES: Process development: novel chemistries, small & nonsmall molecules, bioactive lipids, glycolipids; cGMP manufacture; analytical control of processes: impurity identification characterization, method development, phase-appropriate validation, ICH stability, final product release

THERAPEUTIC AREAS: We have provided our expertise and support across multiple therapeutic areas. A few examples include but are not limited to: CNS, inflammation, anti-infectives, etc.

DR. YVES RIBEILL
CEO

"At SCYNEXIS we deliver innovative solutions that complement our customers' capabilities. Our expert team understands the drug development path and consistently delivers high-quality GMP material while meeting customer timelines. Being recognized in these categories is a reflection of our high standards of safety, quality, and GMP compliance. Our GMP facility has been FDA inspected twice with no 483 issued. It's a pleasure to see our expertise recognized by our peers."

CATEGORIES WON:

Seventh Wave Laboratories

Chesterfield, MO
www.7thwavelabs.com

+1 636 519 4885
Jody DeBold
jdebold@7thwavelabs.com
Key locations: Chesterfield, MO and St. Louis, MO

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical

MAIN SERVICE AREAS:
Bioanalytical, Preclinical

SERVICES & CAPABILITIES: Preclinical PK/PD/TK studies and analysis, pharmacology and disease models, toxicology studies, in vitro ADME, histology, immunohistochemistry/immunofluorescence, pathology, image analysis, stereology, clinical PK/PD analysis, and preclinical consulting

DR. JOHN SAGARTZ
CEO

"Seventh Wave is once again honored to be recognized with multiple CRO leadership awards. Our focus on the needs of our clients, as well as our demonstrated sense of urgency, naturally leads to such recognition. We remain responsive and flexible, and are dedicated to providing excellent project support as a valued member of our clients' R&D efforts."

CATEGORIES WON

SGS Life Science Services

Geneva, Switzerland
www.sgs.com/lifescience

+41 22 739 91 11
Frederic Gaussens
lss.info@sgs.com
Key locations: Belgium, Czech Republic, France, Poland, Spain, United Kingdom, United States

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

MAIN SERVICE AREAS:
Bioanalytical, Clinical

SERVICES & CAPABILITIES: SGS provides Phase I-IV clinical trial management and services encompassing data management, statistics, pharmacovigilance and regulatory consultancy. Laboratory services complete our portfolio including: bioanalysis, biopharmaceutical characterization, and quality control testing.

THERAPEUTIC AREAS: Infectious disease, gastrointestinal, central nervous system, vaccines, respiratory, oncology

ANNE HAYS
Executive Vice President

"As the world's leading inspection, verification, testing, and certification company, SGS is honored to be recognized in the CRO Leadership Awards for a second time. The Life Science Services business strives not only to meet our clients' needs with our existing portfolio of services, but to also develop custom solutions to facilitate their product development processes. Our rankings in the categories can be attributed to our responsiveness to the voice of the customer."

CATEGORIES WON

Spaulding Clinical Research

West Bend, WI
www.spauldingclinical.com

+1 262 334 6020
Amanda Baltz
Amanda.baltz@spauldingclinical.com
Key locations: West Bend, WI and Reno, NV

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

MAIN SERVICE AREAS:
Clinical

SERVICES & CAPABILITIES: Spaulding Clinical Research, LLC provides clinical pharmacology, cardiac core lab services, and is a medical device manufacturer. Spaulding Clinical operates a 135-bed clinical pharmacology unit with 96 full 12-lead telemetry beds.

RANDOL SPAULDING
Founder and CEO

"Spaulding Clinical's passion for innovation is focused on creating customer-driven solutions that enable lower cost and higher fidelity data. New customers are amazed that, for the very first time, their decisions can be made in near real time. Unlike others in the industry, we are so confident in our capabilities we publish our study metrics."

Surpass

CATEGORIES WON

Osceola, WI
www.surpassinc.com

+1 651 433 4277
Amy Stricker-Hume
Amy.Stricker-Hume@surpassinc.com
Key locations: Surpass-Midwest/Twin Cities and Silicon Valley

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical

MAIN SERVICE AREAS:
Preclinical

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THERAPEUTIC AREAS: Cardiovascular, orthopedic, dermatological, neurological, urogenital, pulmonary, gastrointestinal, reproductive, and more

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King of Prussia, PA
www.theoremclinical.com

+1 800 290 5766
Sara Davis
Sara.Davis@Theoremclinical.com
Key locations: Asia Pacific, China, Germany, India, Latin America, North America, United Kingdom

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

MAIN SERVICE AREAS:
Bioanalytical, Clinical

SERVICES & CAPABILITIES: Theorem is a leading provider of comprehensive clinical research and development services, and a forerunner in medical device and drug-device combination trials, with notable capabilities in pharmaceuticals and biologics in a broad range of therapeutic areas.

THERAPEUTIC AREAS: Hematology, cardiovascular, infectious disease & immunology, CNS, endocrinology and metabolism, dermatology, oncology, gastroenterology, respiratory disorders

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DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical

MAIN SERVICE AREAS:
Bioanalytical, Preclinical

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

MAIN SERVICE AREAS:
Bioanalytical, Clinical

SERVICES & CAPABILITIES: Bioanalytical/Immunoassay – biomarker development, method transfer and validation, pharmacokinetic analysis and reporting; Clinical Research – clinical pharmacology, bridging studies, dyna-bridging studies, drug-drug interactions, pharmacodynamic modeling; Clinical Development – protocol development, feasibility, project management, medical monitoring, clinical monitoring, site management, data management, rater training, biostatistics and data analysis, medical writing, regulatory affairs, quality assurance, drug and supply depots, drug safety

THERAPEUTIC AREAS: CNS, cardiovascular, oncology

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The Crystal Ball: Looking At The Future Of Clinical Research

LAURIE HALLORAN, B.S.N., M.S.

Laurie Halloran is president and CEO of Halloran Consulting Group. With over 25 years of experience in clinical affairs management, she is recognized as an industry expert in improving the organizational effectiveness of clinical research programs.

In the life sciences industry, we are always hyper-vigilant about all of the risks involved in product development. Therefore, our "cutting-edge" approaches seem not quite as innovative as other high-tech industries. The time has come for a few key best practices that add efficiency and cost-effectiveness, something the clinical development world desperately needs. In order to confirm my theories, I queried a number of executive-level professional colleagues in pharmaceutical and biotechnology companies, who shared their views off the record. I analyzed my queries and compiled the results into a cohesive discussion below. To add a note of practicality to each, I'll suggest considerations for those who want to make it happen in the present and look toward the future.

TECHNOLOGY AND TRANSPARENCY THAT FACILITATES EVERY FACET OF CLINICAL RESEARCH

As in many other industries, the Internet has created entirely new business models whereby data and information sharing in public domains completely reverses the practices of the past. The day has finally come in life sciences where technology is changing the landscape in terms of real-time availability of data, on everything from patient- and physician-driven protocol design, to using tools online, and transparency in all financial aspects of clinical development, so that companies can conserve their limited resources available for R&D.

In the near future, clinical data will be collected via mobile apps held by patients, transmitted directly, and managed and monitored with significantly less burdensome and time-intensive direct contact in the process. This means that signal detection, safety surveillance, trend analysis, and potential fraud detection will all be completed in real time. Cloud technology and e-systems — with fewer opportunities for human error — will be the wave of the future, greatly speeding the time and increasing the quality of data collected. The company challenges of today are to ensure systems and tools are interoperable and secure. With all of these future advancements come a new set of skills required by our workforce and implementation of completely new methods, to define and manage quality and process.

One major change in the philosophy of companies that will speed up this process more than ever is collaboration between companies, with the ultimate goal of increasing efficiency and improving costs and quality simultaneously. Even the idea of a collaboration is unprecedented to date. In the past 10 years, there were enormous and relatively unsuccessful efforts to decrease direct costs associated with laborious manual processes. After this influx of exertion, technology is finally poised to make the core competencies of the past obsolete. In the near future, clinical research professionals will need to become better at both strategic and relationship management as the adoption of more efficient technology removes many of the onerous processes previously associated with monitoring and data management.

It is likely that the way clinical trials and programs are outsourced will change significantly because of these transformations. There will be an emphasis on partnering with vendors who are producing high-quality deliverables that meet or beat precompetitive cross-industry metrics with lower costs and who make their information available through shared quality data. The CROs that will be leaders are the ones that will invest in providing information and data that is robust, reliable, and available in real time on demand by industry sponsors. These CROs will also differentiate themselves on their ability to provide exemplary, proactive, relationship-based site management services. All of the processes, roles, and the mindsets within and between these relationships will need to evolve for clinical service providers to stay competitive.

PATIENT-CENTRIC FOCUS WILL BE KEY

No matter if sophisticated technology is able to transform the end-to-end production of data needed to demonstrate safety and efficacy, the necessity and presence of patients who produce that data will not change. Companies that are able to connect more directly with patients will have a competitive advantage, because there will be an emphasis on more than just treatment of disease.

In the future, there will also be a focus on the patient with respect to the molecular and genomic characteristics of their disease, and a more precise approach to detecting the basis of, and developing products for, devastating but underserved patient populations who need targeted therapies. While this is another use of Big Data, it ultimately benefits orphan patient populations that had received ineffective treatments in the past because of limitations in accurate diagnoses that are only now beginning to be addressed.

In my optimistic vision of the future, a patient in any part of the world would use their ubiquitous mobile technology to be diagnosed, treated, and selected for a clinical trial. And that trial design would be highly likely to result in a more rapid availability through the marketed product to benefit all who suffer from the illness. If we can envision it, we can create it. Let's get there.

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The Needs And Focus Of Small Sponsors

JONATHAN LEE AND
DEBORAH BISIO DWYER

In this day and age of preferred service provider relationships and/or functional service providers, small pharmaceutical and biotechnology companies present a unique challenge to service providers vying for their business. The resource constraints (both money and people) and time lines are critical, given a narrow or single product development pipeline, little to no revenue stream, and a hyper-focused management team. While these issues may not be unique to small companies, oftentimes the viability of a project, and possibly the company, may lie within two critical aspects — the people and on-time delivery of the project.

THE IMPORTANCE OF IDENTIFYING THE RIGHT PROJECT LEADS

Small companies spend a significant amount of time during the interview process screening potential employees to ensure they have a sense of urgency, a broad base of experience, and the ability to forge collaborative relationships. The expectations of a service provider's project lead are very similar. This necessitates the service provider's project leads to act with a sense of urgency and to take action before issues escalate into problems. As no one likes surprises, the small companies value an early "heads-up" on potential issues, with the knowledge of what is being done to monitor or mitigate them. The intention would not be that the sponsor would vigorously engage at this time, but allow the service provider time to manage the issue at hand. Moreover, if the issue escalates to a challenge, the sponsor is already aware and can quickly engage to jointly determine a course of action. Project leads should constantly be considering if there are additional resources or pockets of expertise within their organization which could be solicited as advisors or engaged formally.

Breadth and depth of experience are critical to the success of the project lead. These traits enable them to be knowledgeable, manage all aspects of the project, and act as a single point of contact. The project may encompass various functional areas such as medical writing, protocol development, site contracts, site start-up, data management, site management, monitoring, etc. Thus, the service provider's project lead would need breadth of expertise to be able to understand the interdependencies of the various departmental processes. They would also need depth to assess and prioritize potential risks and recommend to the sponsor appropriate mitigations.

Not to be overlooked is the service provider's project lead's ability to forge a strong and collaborative working relationship with the sponsor's project lead. Underlying this ability would be the communication skills needed to convey the right message at the right time in a collaborative manner. Just as important as their communication skills is their ability to build trust. This entails the sponsor believing the project lead understands the program and is able to assess and prioritize the risk, provide potential solutions, and then execute with the sponsor's best interest in mind. Having these skillsets in a project lead significantly enhances the joint team's ability to deliver the project on time, which for a small company is crucial.

EXECUTION TACTICS

To assess these various characteristics, we have employed an approach which we call "Speed Dating." This entails a series of three 20-minute targeted interviews with either an individual or panels of people, immediately following each bid defense meeting. Each interviewer or panel is assigned a competency (e.g. conflict resolution, leadership style, influence management) to probe and garner examples during their interview. If the team is not comfortable with the outcome of the interviews, we have asked to assess other potential project lead candidates as part of our consideration. We have found that by employing the speed dating process, we have increased our satisfaction with the project leads. Realizing that we must continue to build these relationships, we continue to invest time, money, and effort after selection with periodic structured face-to-face meetings for the project leads throughout the course of the project.

We recognize that the project leads are only as good as their team. Thus, we acknowledge and celebrate the successes and milestones each service provider contributes to the project. For example, as a service provider achieves their first patient enrolled, we send a small token of our appreciation for the service provider's team to recognize the effort in support of that milestone. We have found that this small token of appreciation goes a long way to highlight our commitment to the team.

In summary, for service providers who recognize the unique nature of small companies' needs and can select the appropriate people, these projects can be some of the most rewarding.

Jonathan Lee is VP of development operations for Cerexa, a subsidiary of Forest Research Institute. His 23 years in the pharma industry include stints at companies such as Nektar Therapeutics/Inhale Therapeutic Systems, Gilead Sciences, and Genentech.

Deborah Bisio Dwyer leads the outsourcing group at Cerexa. She previously worked for Genentech and Chiron Corp.

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Extracting The Value From Outsourcing By Applying Best Outsourcing Practices

GREGORY FIORE, M.D.

Gregory Fiore, M.D., is a Harvard-trained, board-certified physician and former biotechnology CMO. He is founder of SSI Strategy, a consultancy focused on pharmacovigilance and medical affairs.

By its very nature, outsourcing can be a double-edged sword. On one hand you could consider outsourcing as an approach to increase your geographic reach, retain organizational flexibility or a smaller footprint, or achieve some other business goal. On the other hand, such opportunity comes with a bit of risk, such as unexpected cost overruns or poor quality of service. In the most extreme circumstances, patient safety may be put at risk or data integrity compromised to the extent that work needs to be repeated and clinical timelines can be stretched. To unlock the true value of outsourcing while minimizing the risks simply requires you to pay attention to best practice learnings from the legions of outsourced projects that came before yours. Most importantly, proactively structure the outsourced arrangement in such a way as to optimize value and minimize headaches. The following are three best practices that all sponsors should employ to increase the likelihood of success in outsourcing.

1. ENSURE THE OPERATIONS TEAM IS INVOLVED IN PROCURING SERVICES AND DRAFTING THE AGREEMENT.

Often we have seen a procurement team struggle to translate input from the operations team to the vendor; fail to re-engage operations during discussions, even as terms and activities morph from original requirements; and throw the relationship (not even the agreement) over the wall to operations to struggle with. Involving the operations team also will allow the agreement to define the correct metrics and tracking mechanism as well as ensure there is clear understanding of both the intent and wording of agreement.

2. SELECT THE BEST-FIT VENDOR, AND THEN TREAT IT LIKE A PARTNER.

It is important for the sponsor to be realistic about their needs and about who will be a good fit for outsourcing. If budget is a top priority, which is commonly the case, then tradeoffs will be required for certain services, infrastructure, or other components. Once a sponsor has made a realistic selection of the best-fit vendor, the mindset needs to be 100 percent in the direction of partnership (assuming the nature of the services is amenable). Problems need to be solved together, and there is no place for blame. Our view is that there is no perfect vendor, just as there is no perfect team member. What is most important is that the needed skills are present, the spirit and philosophy of the firms are aligned, costs are reasonable, and communication is open.

3. INVEST IN THE RELATIONSHIP.

Another significant mistake is to imagine that an outsourced service provider can do the job alone, except in very limited circumstances. Outsourced activities of any magnitude need directed oversight from the sponsor in the form of an assigned individual or oversight body.

A formal overseer or oversight group can track operational and performance metrics to be sure that expectations are being met from both sides. Proactive monitoring of performance allows for early detection of potential risks (e.g. attrition, need for retraining, additional time spent on an activity, etc.). Additionally, the forum provides an excellent mechanism for the vendor to communicate any suggestions for process improvements that the sponsor should consider. When communication is not forced in this way, both sides tend to stay quiet unless there is an urgent need to speak. Opportunities for program optimization are lost.

IF THIS IS SO EASY, THEN WHY IS OUTSOURCING COMPLICATED?

Outsourcing becomes complex when the sponsor is too busy or inexperienced to properly engage its vendors. In these cases, consideration should be given to working with a third-party advisor or external group to assist the outsourcing effort. When doing so, it is necessary to remember that these firms are also vendors, and best results come from following the same best practice approach with them. Working with an advisor that understands your business and working with them over time affords the best results.

Treating outsourcing as a strategic initiative and following the approaches outlined above will increase the likelihood of success.

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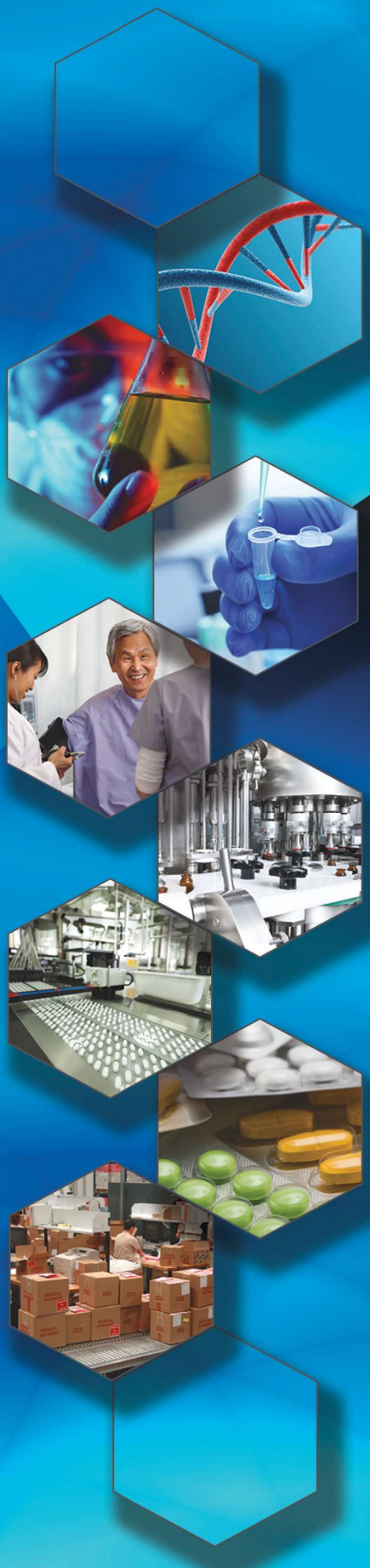

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Impact Of Strategic Outsourcing On QA Oversight By Sponsor Companies

BEAT WIDLER, PH.D.

Dr. Beat Widler is managing partner of Widler & Schiemann Ltd. He has more than 25 years of experience with Roche in Switzerland and the United Kingdom in regulatory affairs, clinical research, quality assurance, and risk management.

Recently, we have been observing a change in the approach to outsourcing — more midsize and large biopharmaceutical companies are shifting to a strategic outsourcing model. Strategic outsourcing generally means assigning work to one or a maximum of two preferred (strategic) partners. The scope of outsourced tasks, however, varies, and no preferred model can be identified. For instance, some sponsor companies outsource all development activities to their partner(s) and only keep a core team to manage the partnership and ensure alignment with functions and services that are considered strategic. Other sponsors limit their strategic partnerships to study management and monitoring, but keep most of the other activities needed to plan, implement, and manage a clinical development program in-house.

WHAT DOES THIS CURRENT TREND MEAN REGARDING QUALITY AND COMPLIANCE?

There is an old principle in quality management: A company can delegate (e.g. outsource) tasks to third parties but will always remain fully responsible and accountable for all decisions, actions undertaken, and data generated by its partners. In other words, for biopharm companies, it's the sponsor's oversight or control of its partners that is paramount to achieving successful quality management.

You've probably heard the phrase "you can delegate tasks but not responsibility." Following this tenet, sponsors must establish a robust process and system that enables seamless control of contracted third parties and of a company's interfacing systems and processes. That process/system must include a way of quickly identifying significant deviations in outsourcing services and ways to trigger effective and timely CAPAs (corrective and preventive actions). CAPAs must lead to the identification of the root cause(s) of a significant GxP deviation. Therefore, the following are essential elements of an effective sponsor–service provider governance model:

- a contract that clearly defines deliverables and roles and responsibilities of each partner
- ways of measuring compliance
- a quality plan that proactively anticipates quality and compliance risks and describes and monitors effectiveness of these plans.

Some sponsor companies and CROs have implemented penalties when targets (e.g. missed timelines or poor compliance) are not met. However, unless these are coupled to objective performance criteria such as KPIs (key performance indicators) and KRIs (key risk indicators), these are not a sufficient oversight measure.

NAVIGATING BETWEEN MICROMANAGEMENT AND LAISSEZ-FAIRE APPROACHES

Micromanaging outsourcing partners is a risk every sponsor needs to avoid. With micromanagement, accountabilities clearly defined in the collaboration contract become undermined as the sponsor starts taking back activities and roles from its partner. Consequently, this affects the efficiency that was expected from the strategic outsourcing alliance in the first place. Typical examples of this sort of risk include using the sponsor's SOPs or systems for tasks performed by the partner or creating complex approval processes for purely operational activities such as clinical trial center selection and onboarding.

But you should also avoid a hands-off approach to outsourcing management. The obvious risk here is a lack of control or oversight. You should be aware that there is lack of oversight when an outsourcing relationship relies on subjective progress reports written by the outsourcing partner, or such reports just address project management priorities (e.g. timelines, study progress) but do not include any objective and verifiable data about quality and compliance. You also don't want those reports to identify deficiencies but do not contain evidence of adequate follow-up by the sponsor.

HOW QUALITY RISK MANAGEMENT TOOLS AND APPROACHES CAN HELP "OUR NAVIGATION"

In our experience, the best approach is when each of the partners agrees on an integrated quality plan that includes:

- structured baseline reviews of systems and protocols (e.g. a failure mode and effect analysis [FMEA])
- tracking and follow-up on leading and lagging risk indicators
- verification of the adequacy of the quality plan through structured comonitoring visits and audits
- a routine process to review and act upon evidence of deviations from the quality plan or newly emerging compliance and quality signals.

Overall, the key to success is outlining structured controls that leverage existing data rather than generating a tide of new questionnaires.

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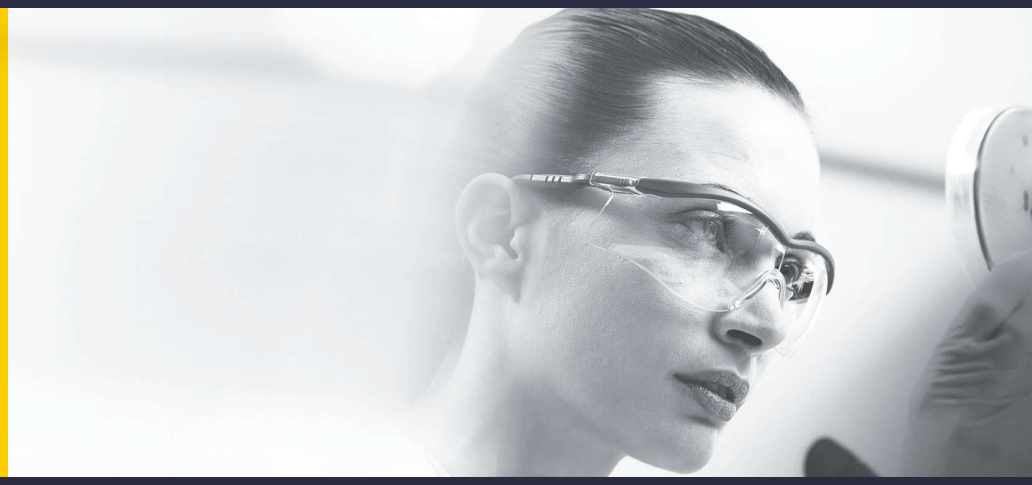

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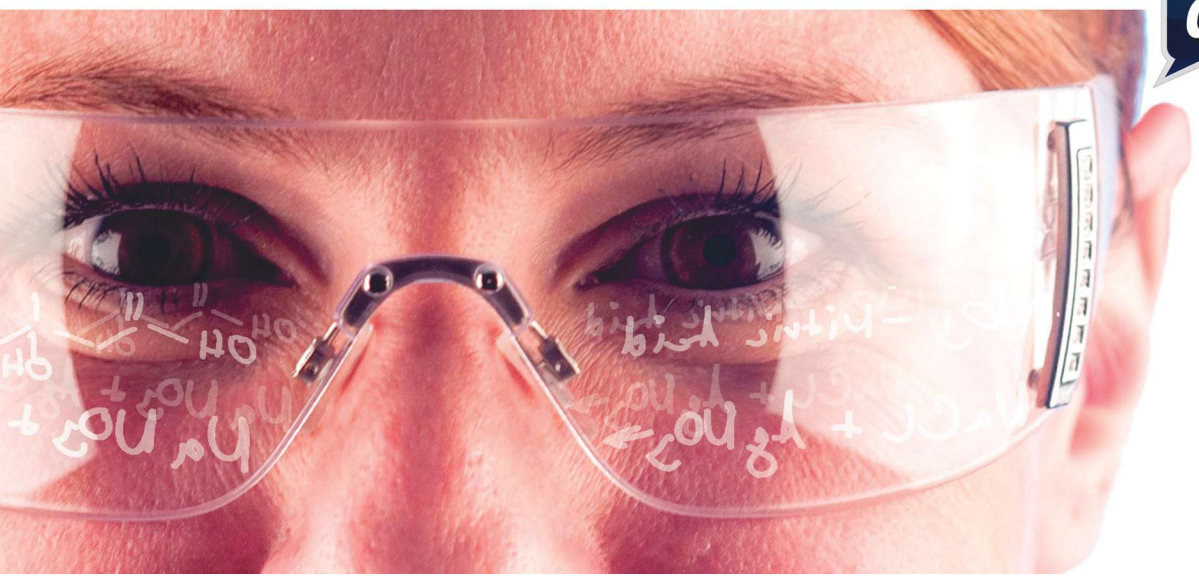

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