A Supplement To
Life Science Leader
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SPECIAL ISSUE:
THE CRO LEADERSHIP AWARDS
See whom you and your peers picked to win!

Expert Insights On Selecting A CRO

Valuable Advice On How To Assess Everything From A CRO's Reliability To Its Regulatory Compliance p. 6

7 WAYS TO MANAGE LIABILITY RISKS FOR A CRO p.34

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Not A Popularity Contest

Last November, *Life Science Leader* launched the inaugural CMO Leadership Awards. The feedback on that issue was overwhelming. So, it is with much pride that I invite you to enjoy our inaugural CRO Leadership Awards Special Supplement. Both the CRO and CMO awards are data driven. I had to clarify this recently to a person who contacted me via an email inquiring when the nomination process for these awards begins and ends. So, let me explain how the Leadership Awards are determined, so readers, sponsors, and vendors can fully understand the process.

On a quarterly basis, Nice Insight conducts a pharmaceutical and biotechnology survey, which is deployed to 40,000 outsourcing-facing biotech and pharma executives. For example, the Q4 2011 sample size was 2,619. Outsourcing companies are rated on six different attributes — quality, reliability, productivity, regulatory, affordability, and innovation, which recently replaced accessibility. Nice Insight then aggregates a year's worth of data to determine which companies rank in the top quartile for each of the above attributes to determine award winners. Thus, CRO Leadership Award winners scored in the top quartile for the previously mentioned categories. As innovation was only recently added as an attribute, perhaps it will be an award category for next year. With regard to affordability, in my discussions with both sponsors and vendors, affordability/low cost is not cited as a primary driver for selecting an outsourcing partner and as such, we are not giving out an Affordability Award.

At *Life Science Leader*, we think having data-driven awards is more objective and valuable than having those given out as a result of a nomination and voting process. In the past, if you wanted this type of information, you hired a third party to survey your customers or you did it yourself. Thanks to survey respondents and the research conducted by Nice Insight, we have taken the guess work out for you. The winners should be proud of these awards because they were determined by data gathered from customers. If your company did not make the grade, consider this a benchmark for developing a plan for improvement.

I look forward to congratulating some of the award winners in person at upcoming trade shows and conferences, such as BIO International and DIA. Keep raising the bar and remember, if you want to win next year, the CRO Leadership Awards are not a popularity contest.

Rob Wright
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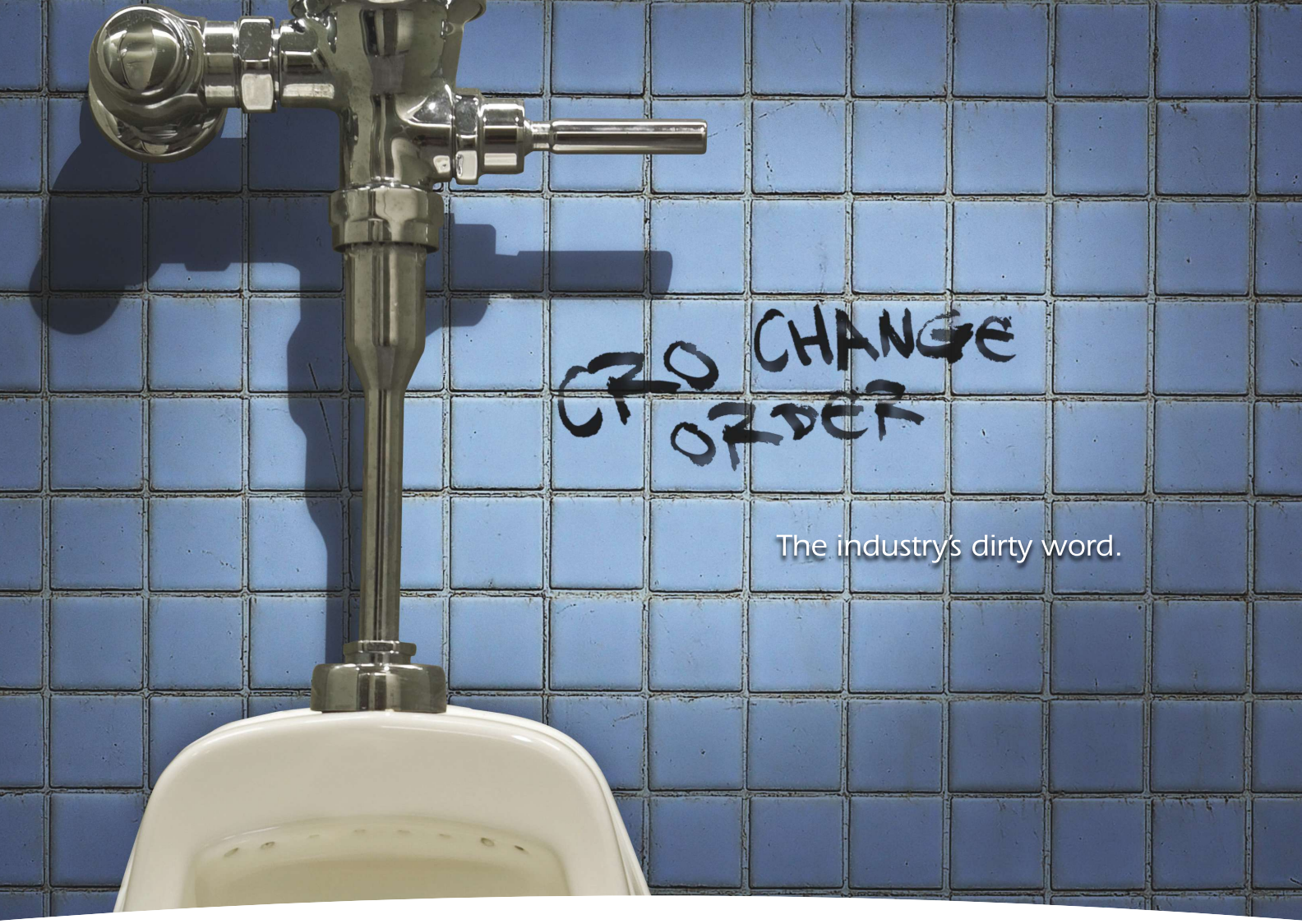
@RFWrightLSL



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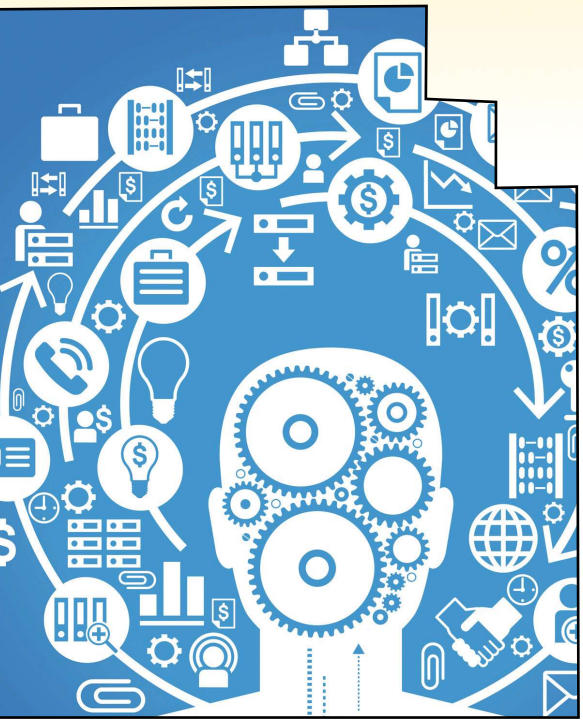


Expert Insight On Selecting A CRO

By Rob Wright

What was once referred to as outsourcing is now commonly called strategic partnering when discussing the business of drug development. In order to successfully strengthen drug pipelines, bio and pharma companies have been increasingly turning to CROs for help. By developing strategic partnerships with CROs, large and midsize companies have been able to capitalize on a reallocation of financial resources, moving from the fixed-cost internal R&D model to one which is more variable and external to the organization.

One of the biggest examples of the implementation of this new model was demonstrated last year by Pfizer, which announced the closing of its Sandwich, UK, R&D facility and the subsequent strategic partnership with two CROs — ICON and PAREXEL. For small and virtual bio/pharma companies, outsourcing of clinical trials has always been part of the business model. For sponsors, the challenge remains how to best qualify, select, and partner with a CRO. But the selection process is not a one-way dialogue. During recent discussions with CROs, most have expressed an interest in being more selective when developing strategic partnerships with sponsors. The goal is to not only match up with expectations and deliverables, but also to align synergistically in the area of corporate culture so the strategic partnership has long-term sustainability.

In an effort to help you gain a greater understanding of the CRO selection process, *Life Science Leader* reached out to seven experts. The resulting roundtable provides insights from highly experienced executives and consultants who can give perspectives from a small biotech startup to a Big Pharma company. The panel includes Peter Carberry, M.D., SVP global development operations, Astellas Pharma US; Peter DiBiaso, head clinical business and development operations, Vertex Pharmaceuticals; Maxine Gowen, Ph.D., president and CEO, Trevena; Jonathan Kfoury, VP, L.E.K. Consulting; Coreen Oei, SVP of clinical operations and project management, BeiGene; Marc Tolkars, senior director clinical operations, Luitpold Pharmaceuticals; and Santosh Vetticaden, president, Global Drug Development Consulting.

WHAT ROLE DOES COST PLAY IN THE CRO SELECTION PROCESS?

Peter DiBiaso, Vertex Pharmaceuticals: While cost efficiency is a key selection consideration and a desired benefit of a CRO partnership, it is not typically a leading criterion. Of greater focus is the evaluation of quality and service expertise (i.e. fit for purpose) for the proposed scope of work. Cost might also play a greater or lesser role according to the type of project being supported. In a more transactional buy — i.e. single study, low study complexity — cost might have a greater influence, whereas in a more strategically driven selection process, other factors will weigh more heavily.

Marc Tokars, Luitpold Pharmaceuticals: For smaller companies, the unfortunate truth is that cost is a major consideration when selecting a CRO. Contracted tasks such as site selection, contracting, monitoring, site payments, and data review are usually not the sole responsibility of either the CRO or sponsor and can often be shared. This provides a cost savings, as the sharing of tasks reduces the CRO's workload while providing sponsors a greater understanding of challenges posed by a trial and faster input toward problem resolution. Some CROs seem reluctant to fully enter into this type of relationship or fail to pass on the savings to sponsors.

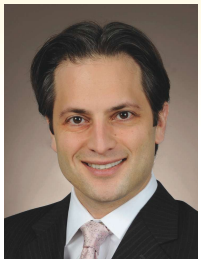
WHAT QUALITY METRICS DO YOU UTILIZE WHEN BUILDING COLLABORATIONS WITH CROs?

Jonathan Kfoury, L.E.K. Consulting: Developing an agreed upon issue esca-


Peter Carberry, M.D., SVP global development operations, Astellas Pharma US


Peter DiBiaso, head clinical business and development operations, Vertex Pharmaceuticals


Maxine Gowen, Ph.D., president and CEO, Trevena


Jonathan Kfoury, VP, L.E.K. Consulting


Coreen Oei, SVP of clinical operations and project management, BeiGene


Marc Tokars, senior director clinical operations, Luitpold Pharmaceuticals


Santosh Vetticaden, president, Global Drug Development Consulting

lation/resolution plan is key to ensuring that the CRO middle and senior management is fully engaged in the study's progress. Sponsors should routinely review reports on what issues were raised and how they were resolved, especially early in the trial when the learning curve is steepest. It is also important to establish a dashboard with the CRO that details leading indicators for the trial each week, i.e. projected completion of enrollment based on active sites and patients enrolled to date, across sites and geographies. This ensures alignment on progress and identifies potential bottlenecks.

Santosh Vetticaden,Global Drug Development Consulting: In general it is recommended that both sponsor and CRO develop a quality plan which addresses the needs of each organization. In addition, it is extremely useful to review the CRO's internal quality plans which often go beyond those areas emphasized by the sponsor. The metrics for quality are too varied to cover in detail, but a few examples include qualifications and training of staff, trial metrics such as enrollment, evaluable patients, reporting time for various activities in data management, and safety reporting.

WHAT NEW TRENDS DO YOU SEE TAKING PLACE WITH CROs?

Maxine Gowen, Trevena: Some CROs are becoming more flexible in taking responsibility for their promises and often refer to this as *risk-sharing*, although I tend to think of it more as *delivering*. The traditional model does not appropriately align incentives, i.e. the longer a trial takes to complete, the more a CRO is paid. This is not sustainable, particularly for loss-making companies with restricted cash availability. CROs will ultimately destroy their customer base if they do not look at their business as relationship-based vs. contract-driven.

Coreen Oei, BeiGene: There has been an increase in pharma-CRO strategic partnerships, especially among the larger pharmaceutical companies and global CROs. These have changed the relationships between CROs and sponsors from tactical/transactional models to those resembling an alliance or partnership. While Big Pharma companies benefit from strategic partnerships, small to midsize biopharma companies may be overlooked. Smaller clients may not view these CROs as having enough capacity to provide the necessary attention in light of demands from larger companies. To guarantee attention from big CROs, smaller biopharma companies need a sizable pipeline of work.

HOW DO YOU GO ABOUT ASSESSING RELIABILITY FOR A CRO?

DiBiaso: As with most business relationships, reliability and trust are dependent on the outcome of your last project. However, there are strategies to encourage greater success. One such approach is establishing mutual collaboration for developing and agreeing to the overall project plans. While in many cases CROs have been selected for particular expertise, this shouldn't discourage the sponsor from contributing to or requiring transparency in the early planning process. This type of input fosters joint ownership of plans and subsequent outcomes. Defining leading key performance indicators that enable teams to make required course corrections or deploy contingent strategies is also essential.

Vetticaden: Because no two clinical programs or trials are exactly the same, it is challenging to define reliability, which may vary depending upon the areas being assessed. In general, it is important to assess the prior reputation, experience, and track record of the CRO being evaluated. Most CROs maintain metrics in areas such as trial completion on schedule and on budget which may provide useful data. Diligence of the CRO's prior experience, competence of key study personnel, organizational structure, plan to deliver, plan for contingencies, and margin of error in their estimates, often provide useful insights for assessing CRO reliability.

HOW WOULD YOU DEFINE ACCESSIBILITY AND WHAT CAN CROs DO TO DEMONSTRATE ACCESSIBILITY AND EXECUTE ON BEING ACCESSIBLE?

Oei: A key requirement during the request for proposal (RFP) process is having the sponsor's questions addressed in a comprehensive and timely manner. I consider accessibility as my company

having visibility with the CRO, as well as the ability to interact with the CRO's senior management. I like to determine if there is transparency and trust in the potential partnership, as I am entrusting the execution of my company's clinical assets to the CRO. Engagement by the CRO's senior management team helps to ensure that my company is getting the right attention and service.

Tokars: In my mind, accessibility is not simply ensuring that the CRO staff assigned to your project is available for a teleconference or meetings to present suggested solutions to project challenges, but instead, to be a true partner, CROs need to allow sponsors transparency into their thought processes and internal deliberations. Talking through the challenges, the history, and potential future remedies with high-level experts, often not intimately involved in the day-to-day operations of the trial, provides a 360-degree review of the problem and often results in discovering the best solution.

WHAT METRIC DO YOU USE TO ASSESS PRODUCTIVITY AND HOW DO YOU WEIGHT THIS WHEN COMPARING DIFFERENT SIZES OF CROs?

DiBiaso: While productivity and overall efficiency are critical components, the high rate of variability across sponsors and CROs in terms of their respective development and operations models makes true industrywide comparisons difficult. Fixed-unit prices, as part of the bidding and contract process, provide some comparative assessments. Functional metrics, such as workload monitoring of average-site-visits-per-monitor, active protocols, and active sites are but a few of the useful metrics when evaluating a CRO by service offerings. It is essential to understand your own resource utilization and effectiveness measures so you have a basis of comparison when CROs cite their own productivity metrics.

Gowen: During the CRO selection process, we evaluate their standards for timelines, turnover rates, meeting usage, i.e. updates vs. real work. An evolving approach during the execution of the study is using earned value (EV) analysis to assess productivity at a high level. Calculating EV creates a relationship between tasks, project costs, and schedule. This provides one objective way of evaluating project health.

WHAT IS YOUR APPROACH TO EVALUATING CROs FOR REGULATORY COMPLIANCE?

Gowen: We solicit the CRO's prior audit and inspection history and the outcomes of those audits/inspections. The CRO's SOPs may also be requested and reviewed to ensure they have adequate processes and standards in place so that, when properly executed, their team adheres to the usual and customary practices. A post-selection CRO audit may identify areas of increased risk for regulatory compliance. In early phase studies, audits can more easily be performed prior to, or as part of, CRO selection.

Vetticaden: Prior to selecting a CRO, evaluate its overall experience, track record, depth of knowledge, qualifications, and experience of regulatory personnel. Supplement this with a review of

prior regulatory inspections, recently completed NDA (new drug application) or other submissions, whereby the CRO had primary responsibility for executing a pivotal Phase 3 trial. Conduct a tailored audit to address sponsor learnings from the review. Once an ongoing relationship with a CRO is established, a phased-in/phased-out approach should be employed. For example, the sponsor should initially review CRO regulatory packages prior to submission. This may lead to iterative interactions, which can eventually be phased out as sponsor and CRO achieve alignment.

WHAT TRICKS OR RESOURCES HAVE YOU FOUND TO BE HIGHLY USEFUL IN THE CRO SELECTION PROCESS?

Peter Carberry, Astellas Pharma US: We have a two-step process that enables us to first identify an initial set of competent vendors through a request for information (RFI) process and then proceed to final selection through the RFP. Blinded to the vendors, we score the RFP responses against a comprehensive set of criteria that can be measured, at least semiquantitatively, and then weight appropriately. The scores are combined to give us a final result. The top candidate(s) are then invited to defend their proposals before we make a final decision.

DiBiaso: Regrettably, there are no tricks to alleviate the time and commitment required for a successful selection. The best approach is investing time to educate the team so they understand their overall role and primary goals. Functional representation needs to be supported by their respective line leadership. This often requires significant alignment and input outside of the regular selection meetings. Executive leadership needs to provide clear and objective guidance to the team. In some cases this can serve as an adjudicator for issues of disagreement, as well as to help the team when there is a challenge in reaching consensus.

WHAT ADVICE WOULD YOU GIVE TO THOSE INVOLVED IN THE CRO SELECTION PROCESS?

Carberry: It is really helpful for sponsors to spend time defining and incorporating business requirements and quantitative expectations in the RFI documents prior to engaging in the

process. Do not preselect in, or out, any vendors, but agree up front on the competencies, capabilities, and performance clinical teams can expect, and allow the RFI process to assist in the selection process. The selection process by itself will not nurture the relationship with the vendor selected. Effective and collaborative governance using measures incorporated in the RFI and RFP process is more likely to result in a successful, productive relationship with quality output.

Gowen: If something does not go well when negotiating the contract, it will probably get worse once the contract is signed. Be methodical and have internal agreement on the necessary scope of work for each CRO and stick to it throughout the RFP process, bid defense, and final selection. When scope definition changes, communicate it clearly and consistently to all involved. Include in the contract, limits for deviation from the plan and give a clear process on what will then happen and who will bear responsibility. Ensure that you have clear instructions regarding change orders, a well-known device for dramatically increasing the cost of your trial. Be clear that you will not pay change orders unless the work has been previously approved.

WHAT ARE SOME OF THE FRUSTRATIONS YOU HAVE HAD IN GOING THROUGH THE CRO SELECTION PROCESS?

Kfoury: Some larger CROs have highlighted their strong experience in a therapeutic area (TA) of focus, but then assigned a team that did not have depth in the field. Ultimately, the CRO project team is critical to a successful trial. A CRO's corporate experience in a given TA doesn't necessarily translate to on-the-ground team member judgment and decision-making ability. Turnover at CROs can be high. It is key to really vet the proposed project team for experience, skills, and most importantly, fit.

Tokars: The greatest frustration we often encounter during the CRO selection period centers around inflexibility. Comparing different CROs for a single project can prove difficult, especially when requesting costs for services in specific formats and breakdowns. Business development groups, almost stubbornly, try to fit their cost algorithms into our preferred formats and often fail miserably, adding error into the estimates. Inflexibility in what services CROs may not want to share with the team also adds a great deal of complexity to the process, as realistically estimating the costs for the shared task proves difficult.

WHAT COULD CROs DO TO MAKE THIS PROCESS EASIER ON YOU?

Kfoury: CROs should work to provide more transparency up front on their proposed team's specific experience within the TA and geographies in question, as well as detail how their projections for cost and timing in similar engagements have mapped (or not) compared to actuality. These simple steps can quickly build comfort with sponsors around a CRO's credibility and capabilities in specific TAs of focus.

Oei: It is always helpful when the CROs provide a proposal that is as comprehensive as possible. The proposal review process is often highly interactive. The CROs should be prepared to turn around queries on the proposal sponsor in a reasonable amount of time.

Vetticaden: CROs need to ensure their RFP submissions include an executive summary highlighting their strategy, key differentiators, costs, timelines, key challenges, and mitigation strategies. It is useful to include options for consideration by the sponsor since it provides insights into the CRO's thought process and abilities. It is also helpful to identify up-front counterparts to the sponsor's relevant team, such as the core study team, so as to rapidly build confidence with the sponsor regarding the CRO's depth and breadth of expertise.

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Tess Pulido-Rios; Research Scientist, Dept. of Pharmacology; Theravance

"...earn my trust and confidence through sustained, timely delivery of accurate results at reasonable cost and contact my team lead directly when you anticipate issues delivering on any of these promises, i.e. speed, cost, and accuracy."

Ralph Lambalot, Ph.D.; Divisional VP, Biologics Dev. & Manufacturing Launch; Abbott Bioresearch Center

"...take ownership in the project, stop nickel and diming us on every clincial study, fully understand the best methods for analysis before initiating the study and providing final project estimates, and most importantly, clearly communicate the progress of the study as milestone payments are made."

Chris Fields; VP Scientific Affairs; Applied Food Sciences Inc.

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Kent Allenby, MD, FACP; VP, Drug Development, Proprietary Products; Dr. Reddy's Laboratories, Inc.

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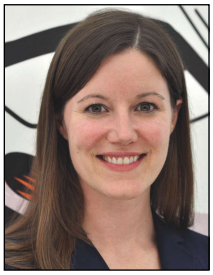

OUTSOURCING INSIGHTS

Advancing Sponsor/CRO Collaborations To Improve Preclinical Throughput

By Kate Hammeke, research manager, Nice Insight

With an overarching goal of optimizing collaborations in the drug development industry, Nice Insight developed a quarterly survey in which prospective, current, and past customers evaluate the communications and performance of 100+ CROs. By conducting primary research on both outsourcing practices and contractor performance, the information generated can help save time and money spent on the partner selection process by enabling the sharing of knowledge among peers on the sponsor side of the industry. Additionally, CROs can review quantified feedback from sponsors to gain an understanding of how well their businesses are known and perceived across the pharmaceutical and biotechnology industry.

Developing the research tool started with identifying the drivers that influence partner selection, as well as understanding the nuances of the different types of outsourcing relationships — including tactical service providers, preferred vendors, and strategic partnerships — and the value each type of relationship can bring to a sponsor. The Nice Insight team conducted in-depth interviews with industry executives in order to design a survey that would offer insight on key performance measures across the industry. We've learned in this short time since publishing the first report in March 2011 that the right relationship between sponsor and CRO will open the doors to further innovation.

Nice Insight's survey randomly presents approximately 30 questions to each respondent in order to collect baseline information with respect to customer awareness and customer perception. Five levels of awareness, from "I've never heard of them" to "I've worked with them" factor into the overall customer awareness score. The customer perception score is based on six key drivers in outsourcing: quality, innovation (which replaced accessibility for 2012), regulatory compliance, pricing, productivity, and reliability. Respondents rank the drivers to determine the weighting applied to the overall score.

The value of the information available through Nice Insight lies in helping users to quickly identify potential partners, while establishing industry benchmarks that show where each CRO is positioned relative to industry averages and its direct competitors.

In the first year, the survey evolved rapidly as direct feedback from Nice Insight clients helped identify further areas of curiosity — such as when (during which phase of development) sponsors are most likely to engage outsourcing services. Survey respondents revealed a dramatic change in early-stage practices, with 50% indicating the company they work for engages CROs during the discovery phase — a practice almost unheard of a decade ago. As intellectual property rights and regulatory standards strengthened, the complexity of projects offered to subcontractors increased.

A SHIFT TO EARLY-STAGE TESTING

A key benefit of finding the right CRO to engage for discovery work is the increased potential for more molecules to pass into preclinical trials. After all, according to the book *Approaches to Assessing Drug Safety in the Discovery Phase,* "it has been estimated that a 10% improvement in predicting future failure before the initiation of expensive and time-consuming clinical trials could save upwards of $100 million on the costs associated with drug development." As such, the drug development industry has shifted attention toward developing, authenticating, and executing more proactive testing standards in earlier stages.

It is essential for contract service providers to continually communicate their presence and offering to the industry at large, as well as develop targeted messaging for specific audiences. This combined approach increases the likelihood of being on the radar of outsourcing sponsors in general and the possibility of being considered for specific project. As entry into the market becomes more challenging, CROs can benefit from keeping up on outsourcing trends, especially how practices and desired services vary among the different sponsor groups, and arming themselves with information. Both sponsors and CROs can benefit from understanding how customer perception serves as a short-term measure for maintaining clients, and customer awareness serves as long-term measure of sustainability.

**CRO Leadership Awards were based on Q4, 2011 survey results. Q1, 2012 results are currently available on nice-insight.com*

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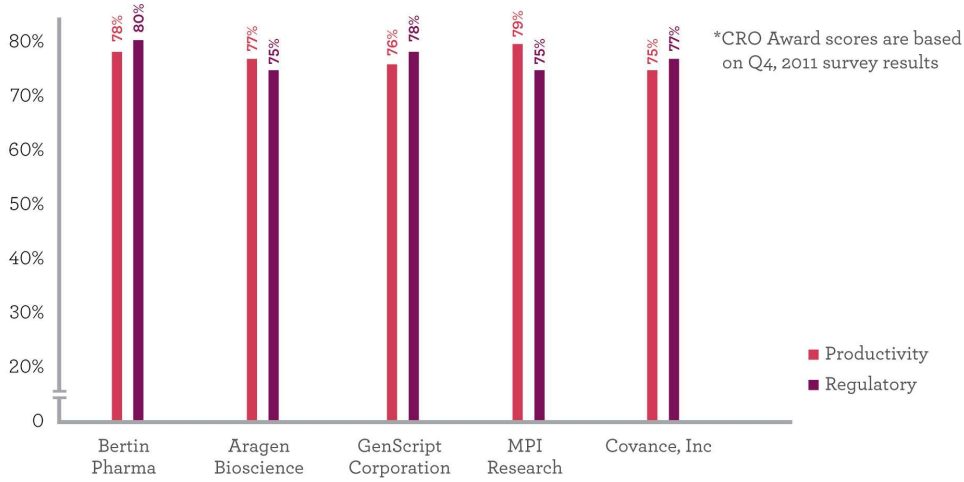
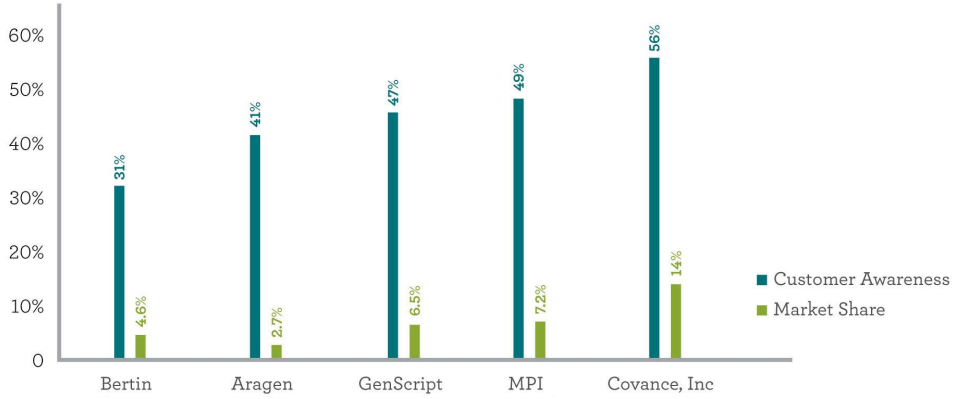


NI Customer Awareness and Toxicology Market Share



Survey Methodology: The Nice Insight Pharmaceutical and Biotechnology Survey is deployed to 40,000 outsourcing-facing pharmaceutical and biotechnology executives on a quarterly basis [Q4 2011 sample size 2,619]. The survey is composed of 1,000+ questions and randomly presents ~30 questions to each respondent in order to collect baseline information with respect to customer awareness and customer perceptions of 300 companies that service the drug development cycle. More than 1,200 marketing communications, including branding, websites, print advertisements, corporate literature, and trade show booths are reviewed by our panel of respondents. Five levels of awareness from "I've never heard of them" to "I've worked with them" factor into the overall customer awareness score. The customer perception score is based on six drivers in outsourcing: Quality, Accessibility, Regulatory Compliance, Pricing, Productivity, and Reliability, which are ranked by our respondents to determine the weighting applied to the overall score.

If you want to learn more about the report or how to participate, please contact Victor Coker, director of business intelligence at Nice Insight, by sending an email to niceinsight.survey@thatsnice.com.

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Atlantic Analytical Laboratory
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BRI Biopharmaceutical Research Inc.
Brixham Environmental Laboratory
Charles River Laboratories International, Inc.
Chiltern
Cirion Clinical Trial Services Inc.
Covance, Inc.
Critical Path Services, LLC
Diteba Research Laboratories Inc.
EAG Life Sciences
Encompass Pharmaceutical Services
Exova
Frontage Laboratories, Inc.
Galbraith Laboratories, Inc.
GenScript Corporation
INC Research
LabCorp Clinical Trials
Lambda Therapeutic Research
Laxai Avanti Life Sciences Pvt. Ltd
McCrone Associates, Inc.
Microbac Laboratories, Inc.
MPI Research
Optivia Biotechnology Inc
Pacific BioLabs
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PRA
Product Safety Labs
Quantex Laboratories
Quintiles
ReSearch Pharmaceutical Services
SCYNEXIS, Inc.
SGS Life Science Services
SIRO Clinpharm
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Tandem Labs
Warnex Inc.

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Arista Laboratory
Atlantic Analytical Laboratory
Bertin Pharma
Brixham Environmental Laboratory
Chiltern
Covance, Inc.
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McCrone Associates, Inc.
MPI Research
Optivia Biotechnology Inc
Quantex Laboratories
Quintiles
ReSearch Pharmaceutical Services
SCYNEXIS, Inc.
SIRO Clinpharm
SSCI, a division of Aptuit
Warnex Inc.

RELIABILITY AWARD

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- Agilent Technologies
- Agilux Laboratories
- Arista Laboratory
- Bio-Technical Resources
- BRI Biopharmaceutical Research Inc.
- Chiltern
- Covance, Inc.
- Critical Path Services, LLC
- Dainippon Sumitomo Pharmaceuticals
- EMD Millipore
- Encompass Pharmaceutical Services
- Eurofins Scientific
- Huntingdon Life Sciences
- ICON plc
- Laxai Avanti Life Sciences Pvt. Ltd
- Optivia Biotechnology Inc
- PRA
- Product Safety Labs
- Quintiles
- Seventh Wave Laboratories
- SIRO Clinpharm
- Toxikon Corporation

ACCESSIBILITY AWARD

- Accugenix Inc.
- Agilux Laboratories
- Aragen Bioscience
- Atlantic Analytical Laboratory
- Charles River Laboratories International Inc.
- Chiltern
- Cirion Clinical Trial Services Inc.
- Critical Path Services, LLC
- Encompass Pharmaceutical Services
- Galbraith Laboratories, Inc.
- Laxai Avanti Life Sciences Pvt. Ltd
- Optivia Biotechnology Inc.
- PAREXEL International
- ReSearch Pharmaceutical Services
- SIRO Clinpharm

QUALITY AWARD

- Accugenix Inc.
- Agilux Laboratories
- bioRASI
- Chiltern
- Critical Path Services, LLC
- Dainippon Sumitomo Pharmaceuticals
- EMD Millipore
- Encompass Pharmaceutical Services
- Exova
- Huntingdon Life Sciences
- ICON plc
- LabCorp Clinical Trials
- PAREXEL International
- Product Safety Labs
- Quintiles
- SGS Life Science Services
- SSCI, a division of Aptuit

As Presented By:

Life Science Leader

Based On The Research Of:

niceinsight QUARTERLY INTELLIGENCE

Accugenix, Inc.
Newark, DE
www.accugenix.com
(800) 886-9654

Key locations: Newark, DE; Germany
Contact: Mike Anderson
sales@accugenix.com

Main Service Areas: Bioanalytical

SERVICES & CAPABILITIES: Our laboratory has tested and identified more microorganisms than any other company or service laboratory. This has allowed us to develop and refine our validated proprietary libraries and methods of interpretation unrivaled in the industry.

THERAPEUTIC AREAS: We specialize in microbial identification and strain typing of environmental isolates from sterile and aseptic manufacturing production sites. Our sequence-based genetic microbial identification service, AccuGENX-ID®, is considered the industry's "gold standard" method of choice for moderate and complex applications, such as high-risk manufacturing, sterility failures, final product releases, and testing for sterile fill facilities. AccuPRO-ID®, a proteotypic method based on MALDI-TOF mass spectrometry technology, is an ideal high value/low cost solution for routine environmental monitoring and primary screening needs.

KEY INDUSTRY PARTNERS: For more than 20 years, we have served the bio-pharmaceutical, medical device, nutraceutical, personal care, and cosmetics industries — providing the fastest, most accurate, and reliable microbial identification services to more than 1,000 global facilities.

"Accugenix provides accurate, fast, and cost-effective microbe species identification and strain typing services. By using innovative technologies like DNA sequencing and MALDI-TOF and developing full coverage libraries, Accugenix has become the industry leader. Production risk is minimized with the accurate identification of microbes. Online sample submission, sample status and identification reports, along with our staff of experts are committed to providing high quality, cost-effective, and fully supported solutions."
— Douglas Smith, president and chief executive officer

Advion Bioanalytical Labs —
A Quintiles Company
Ithaca, NY
www.quintiles.com/clinical-services/
bioanalytical-laboratories

(607) 266-0665
Key locations: Ithaca,
NY; Manassas, VA; Indianapolis, IN
Contact: Thomas Kurz
thomas.kurz@quintiles.com

Main Service Areas: Bioanalytical

SERVICES & CAPABILITIES: We provide GLP-compliant bioanalytical and immunogenicity testing services in support of pharmacokinetic and biomarker studies, as well as in vitro ADME screening, metabolite profiling, and definitive metabolite identification services.

"Advion Bioanalytical Labs is one of the largest and most respected bioanalytical laboratories. In particular, the company is known for 1) scientific excellence, 2) leadership in regulatory compliance, 3) extensive experience in GLP bioanalytical science, and 4) innovation and method development experience. Providing GLP-compliant bioanalytical services since 1993, our staff includes renowned bioanalytical scientists including Dr. Stephen Lowes and Dr. Jack Henion, head of the research group that invented IonSpray LC/MS/MS."
— Thomas Kurz, Vice President ——Strategy and Commercial Operations

Agilent Technologies — Agilent Discover Services (formerly BIOCIUS Life Sciences)
Wakefield, MA
www.agilent.com
(781) 928-2779

Key locations: Wakefield, MA;
Waldbronn, Germany
Jennifer Rossi
jennifer.rossi@agilent.com

Main Service Areas: Bioanalytical, Preclinical

SERVICES & CAPABILITIES: Lead Discovery — assay development and screening, *in vitro* ADME — CYP450 Inhibition, metabolic stability, permeability

THERAPEUTIC AREAS: Oncology, epigenetic targets, metabolic disorders, anti-infectives, neurology, inflammation, and cardiovascular disease

KEY INDUSTRY PARTNERS: Most of the top global pharmaceutical companies and numerous emerging to larger biotech companies

"We are very pleased to be recognized for our leadership in the CRO industry. Agilent's RapidFire instrumentation and research services are highly valued by leading drug discovery researchers around the globe, and this acknowledgment by our peers validates our critical role. Our commitment to this industry will continue to grow and get stronger as we fully leverage Agilent's breadth of global resources."
— Nick Roelofs, president, Agilent Life Sciences Group

BASi

BASi (Bioanalytical Systems, Inc.)
West Lafayette, IN
www.basinc.com

Key locations: West Lafayette, IN;
Mount Vernon, IN
Contact: Albert Hidalgo
ahidalgo@basinc.com

Main Service Areas: Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: BASi is a drug development services firm that offers a variety of services along the entire drug development continuum, including drug discovery, bioanalytical, toxicology, pharmaceutical analysis, and stability services.

THERAPEUTIC AREAS: analgesic, antidiabetic, antibiotic, antiviral, biomarker, cardiac, gastric, neurology/CNS, oncology, steroid, pain

KEY INDUSTRY PARTNERS: XenoGesis Limited, a BioCity Nottingham company; Pinnacle Technology of Lawrence, Kansas; Data Sciences International (DSI), the global leader in implantable telemetric physiological monitors, serving contract research organizations, pharmaceutical manufacturers and academic research institutions.

"I am very pleased that BASi has been recognized with a CRO Leadership Award for our excellent regulatory compliance and quality assurance. This is a tribute to all our staff at BASi. Our experienced scientific team strives to give clients confidence in meeting key milestones and having a successful review and audit of data. We know regulatory excellence is important to a successful partnership."
—Anthony S. Chilton, Ph.D., president and chief executive officer

bertin pharma

Bertin Pharma
Montignyle Bretonneux France
www.bertinpharma.com
(33) 139-306-220

Key locations: Orleans, France; Artigues, France
Contact: Xavier Morge
info@bertinpharma.com

Main Service Areas: Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Pharmaceutical development and clinical supplies, *in vitro* and *in vivo* microbiological safety assessments, preclinical and clinical studies, ADMET, biotransformation, biomarkers assay and bioanalysis, protein and host cell protein analysis, immunomonitoring, immunogenicity, formulation

THERAPEUTIC AREAS: All therapeutic areas

"We are very pleased and proud that Bertin Pharma is recognized as one of the leading companies for productivity and regulatory categories. It is valuable information coming directly from our customers. I share this recognition with my teams, highly qualified and involved in the rendering of quality work and accuracy. On behalf of Bertin Pharma, thank you for this distinction that makes us a little more visible each day."
— Xavier Morge, Bertin Pharma

bioRASI

bioRASI
Aventura, FL
www.biorasi.com
(786) 388-0700

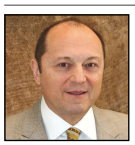
Key locations: California, Serbia, Florida, India, Russia, Ukraine
Contact: Luke Passler
lpassler@biorasi.com

Main Service Areas: Clinical

SERVICES & CAPABILITIES: bioRASI, a full-service global CRO, optimizes clinical programs around quality, time, industry acceptance, cost, and service level. bioRASI offers optimized solutions through its focused divisions: drugs, biotherapeutics, and medical devices.

THERAPEUTIC AREAS: Dermatology, ophthalmology, endocrinology/women's health, cardiovascular, central nervous system, infectious diseases, oncology, gastroenterology, pulmonary, and others

KEY INDUSTRY PARTNERS: Russian Academy of Sciences, Research Corporation Technologies (RCT), and Hospital Corporation of America



"bioRASI is pleased that our sponsors recognized us in the category of quality. Quality is one of the main criteria of our optimization-focused bioRASI Process Infrastructure (BPI). Striving to improve quality at bioRASI goes far beyond conventional approaches of adhering to regulatory requirements. We are focused on increasing the probability of trial success through strategies such as reducing trial-induced variability. Among other methods, this is accomplished through bioRASI's proprietary interactive training of investigators and patients."
— Boris Reznik, Ph.D., chairman

BRI Biopharmaceutical Research Inc.
Vancouver, BC Canada
www.bripharm.com
(604) 432-9237

Key location: Vancouver, British Columbia
Contact: Clara Faan, VP sales
cfaan@bripharm.com

Main Service Areas: Bioanalytical, Preclinical

SERVICES & CAPABILITIES: GLP bioanalytical assays supporting tox and clinical PK, tumor cell lines and tumor xenograft models based on patient-derived orthotopic grafting, *in vitro* drug metabolism/ADME/bioavailability, *in vivo* drug metabolism and pharmacokinetics in tox species, drug substance and drug product stability program on clinical products

THERAPEUTIC AREAS: Supported many oncology preclinical and clinical programs and other therapeutic areas (antiviral, anti-inflammatory, and cardiovascular), lymphomas

KEY INDUSTRY PARTNERS: AP Sciences Inc. for cryopreserved hepatocytes

"For nearly two decades, BRI has become recognized by its pharma and biotech clients for providing fit-for-purpose bioanalytical and DMPL studies supporting IND-enabling preclinical and clinical development. On behalf of our study teams and management at BRI, I am very pleased to have contributed to our clients' successful milestones over the years."
— David Kwok, CEO

Brixham Environmental Laboratory
Brixham, Devon, UK
www.Brixham-lab.com
44 (0) 1803 88 44 00

Key location: Brixham, Devon, UK
Contact: Matthew Porter
matthew.porter@astrazeneca.com

Main Service Areas: Bioanalytical

SERVICES & CAPABILITIES: Support to environmental risk and impact assessments; assessment of acute and chronic effects to aquatic organisms, including full fish-life-cycles; assessment of potential to biodegrade/persist in the environment; analytical chemistry; all GLP-compliant and to world-wide regulations

THERAPEUTIC AREAS: Regulatory ecotoxicology, environmental fate testing, analytical chemistry, physico-chemical analysis, mathematical modeling

"Our knowledge of environmental regulations, both current and future, is supported by highly qualified staff who are among leading experts contributing to the process of developing and refining forthcoming guidelines for environmental testing. Our pricing is competitive and our recently refurbished, state-of-the-art testing and husbandry facilities offer one of the best equipped laboratories of its kind in Europe, if not the world."
— Paul Duckett, laboratory director

Charles River Laboratories International, Inc.
Wilmington, MA
www.criver.com
(781) 222-6000

Key locations: Canada, France, Germany, Italy, Japan, United Kingdom, United States
askcharlesriver@crl.com

Main Service Areas: Bioanalytical, Preclinical

SERVICES & CAPABILITIES: Preclinical services that include general and specialty toxicology, research models and services, pathology services, laboratory sciences, agrochemical and animal health product development, biopharmaceutical testing and manufacturing

THERAPEUTIC AREAS: Whatever your area of research, Charles River provides the products and support services necessary for the discovery and development of the novel treatments you are searching for to help patients live healthier lives. A few of the many therapeutic areas include cardiovascular, endocrine/metabolic, oncology, skeletal disease, central nervous system, inflammation ophthalmology, vaccines, biosimilars, and cellular therapies.

KEY INDUSTRY PARTNERS: Charles River partners with pharmaceutical and biotechnology companies, government agencies, and leading academic institutions around the globe to accelerate their research and drug development efforts.

"At Charles River, we invest continuously in our people and portfolio to ensure that we have the expertise as well as the products and services to support our clients' drug development programs. Our passion for scientific excellence is a strong foundation for client relationships, which play a pivotal role in developing the flexible research platforms that are integral to delivering innovative health solutions. We are pleased that the marketplace recognizes, with this award, our commitment to clients."
— James C. Foster, chairman, president, and chief executive officer

Chiltern
Slough, UK
www.chiltern.com
44 (0) 1753 512 000

Key locations: Asia Pacific, Eastern Europe, Latin America, North America, Western Europe
Contact: Stuart McGuire
stuart.mcguire@chiltern.com

Main Service Areas: Clinical

SERVICES & CAPABILITIES: Early phase, global clinical development, late phase, biometrics, medical and regulatory affairs, resourcing solutions

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

KEY INDUSTRY PARTNERS: Endpoint, Medidata, Oracle, Datalabs

"Chiltern is delighted to be recognized as a CRO leader in quality, reliability, accessibility, productivity, and regulatory categories. Chiltern has been serving clients with pride for 30 years and has established a track record around the world as an expert, efficient, and highly responsive full-service CRO. It is a privilege to be recognized by members of the pharmaceutical industry that we serve and a great pleasure to accept this award on behalf of all of the people at Chiltern."
— Glenn Kerkhof, CEO

Cirion Clinical Trials Services, Inc.
Laval, Quebec Canada
www.cirion.com
(450) 682-2231

Contact: Marc Routhier, VP, business development
routhierm@cirion.com

Main Service Areas: Bioanalytical, Clinical

SERVICES & CAPABILITIES: Contract research laboratory, global central laboratory, assay development and GLP validation, biologics, biosimilars, biomarkers, immunology, virology, molecular biology, cell based assays, and microbiology

"On behalf of all CIRION's team, I would like to thank you for this award. Since 1996, CIRION has been in constant growth and has developed strong expertise in the field of large molecules. We also want to take this opportunity to acknowledge the trust of our growing clientele throughout these years."
— Dr. Sylvain Desrochers, Ph.D., president and CEO

Critical Path Services, LLC
Garnet Valley, PA
www.criticalpathservices.com
(610) 558-3001

Key location: Garnet Valley, PA
Contact: Larry M. Mallis, Ph.D.
larry.mallis@criticalpathservices.com

Main Service Areas: Bioanalytical, Preclinical

SERVICES & CAPABILITIES: GLP bioanalytical method development, validation, and trace level quantitation from plasma, serum, and tissue matrices; toxicology; safety assessments; and GHS classification services; technical writing (reports, publications, dossier preparation)

"Our clients appreciate our focus on meeting their needs. The regulated sciences is a complex industry, and our clients have many demands with little room for error. As a company, our chosen core values are passion for excellence, integrity in practice, and drive with flexibility. Our staff all strive to live this daily and find ways to keep our customers delighted with our work products."
— Julie Eble, PhD, CEO

EAG Life Sciences
Maryland Heights, MO
www.eaglabs.com/ls
(800) 659-6059

Key locations: Maryland Heights, MO; Sunnyvale, CA; East Windsor, NJ; Chanhassen, MN
Contact: Katie Grayson
info.lifesciences@eaglabs.com

Main Service Areas: Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Analytical research and development, method development, method validation, characterization, extractables and leachables, stability services, quality control testing, bioanalytical services, custom synthesis, compendial assays and monographs, medical-device testing, combination drug-device testing, impurity/segradant identification

THERAPEUTIC AREAS: We conduct studies within all therapeutic areas and are specialists on drug delivery systems such as drug substances, excipients, oral dosages (tablets, capsules), topical dosages (creams, ointments, lotions), liquid dosages (solutions and suspensions for oral, ophthalmic, otic, and parenteral delivery), transdermal, medical devices, combination devices.

"We are highly ranked by our clients, because of our very experienced scientific team — our scientists are novel thinkers, ready to face complex challenges. We have well established teams, with dedicated project managers committed to quality, on-time delivery, and communication, keeping clients informed every step of the way. Our long history of providing analytical solutions, along with the right fit, talent, and focus, is the reason EAG Life Sciences has earned these rankings."
— Craig Morley, general manager of EAG Life Sciences

Eurofins Scientific N.V.
Kraainem Belgium
www.eurofins.com
(02) 766-16-40

Key locations: France, Germany, India, Netherlands, New Jersey, Singapore, Virginia

Main Service Areas: Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Global central laboratory; microbiological and anti-infective analysis; biomarkers and immunogenicity testing; DMPK/TK large and small molecules; Phase 1, 2a; bio-assays; toxicology/pharmacology/REACH; genomics.

"For the biopharmaceutical clients what matters is to get the product to the market in the fastest possible way. This implies professionally executed services and good, open communication. I definitely think that this is, together with our entrepreneurial culture, where we make the difference."
— Dr. Gilles Martin, CEO

Exova
Mississauga, Ontario, Canada
www.exova.com
(905) 822-4111

Key locations: Camberly, United Kingdom, Edinburgh, United Kingdom; Santa Fe Springs, CA
Contact: Robert Marner, VP, sales and marketing
robert.marner@exova.com

Main Service Areas: Bioanalytical, Preclinical

SERVICES & CAPABILITIES: Clinical trial materials manufacturing and supply, pharmaceutical batch release testing, pharmaceutical outsourcing solutions, pharmaceutical polymer testing, pharmaceutical stability studies testing lab, preformulation and formulation development, raw materials testing, regulatory consulting services

"Exova prides itself on servicing its pharmaceutical and medical device customers to their complete satisfaction. We take great care to ensure our test results are of the highest quality and delivered on time in an efficient manner. Our strengths are our people and our trusted client relationships. We are extremely pleased to be recognized as a leader by our customers in the categories of Quality, Productivity, and Regulatory knowledge. On behalf of Exova, I would like to thank you for this award, which will be shared and communicated among all our dedicated employees."
— Michael Hincks, executive vice president of health sciences, Americas

FRONTAGE moving your compound forward

Frontage Laboratories, Inc.
Exton, PA
www.frontagelab.com
(610) 232-0100

Key locations: China; Exton, PA; Malvern, PA; Hackensack, NJ
Contact: Ajay Sharma
asharma@frontagelab.com

Main Service Areas: Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: BioAnalytical services, method development, clinical biomarkers, sample analysis, PD modeling, LC-MS/MS analysis, preclinical services, *in vitro* ADME, *in vivo* PK, exploratory toxicology, safety pharmacology, clinical services, clinical study design, regulatory consulting, project management

THERAPEUTIC AREAS: CNS, dermatology, GI, infectious diseases, inflammation, men's health, metabolic, oncology, ophthalmology, pain, women's health

KEY INDUSTRY PARTNERS: Spaulding Clinical, Document Solutions Group

"This CRO Leadership Award recognizes the successful approach Frontage takes toward helping clients manage FDA reviews to secure approvals for innovative, biologic, and generic pharmaceutical products in a reputable and compliant manner. When we initiate drug development and commercialization projects with our clients, we start by discussing their regulatory goals and then incorporate Quality by Design and rational drug development principles to ensure their programs advance smoothly through the FDA review process."
— Song Li, chairman and CEO

GALBRAITH LABORATORIES, INC.

Galbraith Laboratories, Inc.
Knoxville, TN
www.galbraith.com
(865) 546-1335

Contact: Darryl Hendricks
darrylhendricks@galbraith.com

Main Service Areas: Bioanalytical

SERVICES & CAPABILITIES: Elemental analysis, analytical laboratory, chemical analysis, trace analysis, testing laboratory, metals analysis, method development, method validation, raw materials analysis, contract analytical laboratory, contract testing lab, pharmaceutical testing, regulated studies, material analysis, mineral analysis, physical property testing, monographs, assays, food additive testing, industrial testing, environmental testing, wet chemistry

"Being recognized for the things we work hard at every day is very rewarding. For more than sixty years, Galbraith Laboratories has striven to provide our clients with services that reflect the highest standards of integrity and quality in the analytical chemistry field. As such, we are honored to be recognized for our service to the pharmaceutical industry. We feel this reward is a reflection of the dedication and hard work of all our analytical chemists, management staff, and support personnel."
— Darryl Hendricks, director of technical services

Huntingdon Life Sciences
Working for a better future

Huntingdon Life Sciences
East Millstone, NJ
www.huntingdon.com
(732) 873-2550

Key locations: Cambridgeshire, UK; Suffolk, UK
sales@princeton.huntingdon.com

Main Service Areas: 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, and environmental risk assessment

"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 this award."
— Brian Cass, managing director

ICON plc
Leopardstown, Dublin, Ireland
www.iconplc.com
353-1-2912000

Key locations: China, Germany, India, Ireland, Japan, United States
Contact: Paul Colombo, VP sales, U.S. business development
info@iconplc.com

Main Service Areas: Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Phase I-IV clinical trial design, management and review, clinical pharmacology, bioanalytical and central labs, biomarkers, pharmacodynamic/pharmacokinetic analysis, data management, medical and safety, biostatistics, interactive technologies, patient recruitment, medical imaging, contract resourcing

THERAPEUTIC AREAS: Oncology, cardiovascular, CNS, endocrine and metabolic disorders, biosimilars, gastrointestinal, transplant and immunology, infectious disease and vaccines, dermatology, haematology, musculoskeletal, respiratory, genitourinary

KEY INDUSTRY PARTNERS: Pfizer; Ely Lilly; Shire; Bristol-Myers Squibb

"ICON's leadership ranking in this industry survey is testament to the expertise and dedication of ICON employees around the world who deliver quality programs to clients. We will continue to be a proactive and innovative provider of solutions that help clients maximize the effectiveness of their R&D activities and bring new drugs to market more cost effectively and efficiently."
— Dr. Steve Cutler, group president, clinical research services

INC Research
Raleigh, NC
www.incresearch.com
(919) 876-9300

Key locations: Australia, China, India, Mexico, United Kingdom, United States
Contact: John Musante, senior VP, business development
info@incresearch.com

Main Service Areas: Clinical

SERVICES & CAPABILITIES: Phase I - IV clinical services include biometrics, clinical monitoring, drug safety, FSP /strategic alliances, patient recruitment/retention, project management, regulatory affairs, strategic consulting

THERAPEUTIC AREAS: Cardiovascular, CNS, dermatology, endocrinology, gastroenterology, immunology, infectious diseases, inflammation, oncology, ophthalmology, respiratory with special expertise in pediatrics, and women's health populations

"INC Research prides itself on building strong relationships with its customers and consistently and efficiently delivering quality clinical development services on their behalf. This focus is the essence of the Trusted Process®, our proprietary, metrics-driven clinical outsourcing methodology specifically designed to reduce variability and increase productivity while remaining flexible to meet our customers' complex and changing needs."
— Jim Ogle, CEO

LabCorp Clinical Trials
Cranford, NJ
www.labcorp.com/clinicaltrials
(877) 788-8861

Key locations: Belgium, Canada, China, Germany, Singapore, United States
Contact: Shailesh Maingi
clintrialssales@labcorp.com

Main Service Areas: Clinical

SERVICES & CAPABILITIES: Biomarkers, biorepository, coagulation, companion diagnostics, cytogenetics, endocrinology, flow cytometry, infectious disease, *in vitro* diagnostic device, pharmcogenetics, Phase 1, safety

THERAPEUTIC AREAS: Laboratory services for all therapeutic areas

KEY INDUSTRY PARTNERS: Monogram Biosciences, a LabCorp Company; Tandem Labs, a LabCorp Company; The Biomarker Factory, a venture with Duke University Medical Center; M.U.R.D.O.C.K. Study, The Measurement to Understand Reclassification of Disease of Cabarrus and Kannapolis, an initiative between Duke University and LabCorp Biorepository; David H. Murdock Research Institute (DHMRI)

"LabCorp approaches each new project with an innovative, scientific mindset. This pioneering attitude has led to many advances across the life sciences. The goal with the development of each new tactic is to use our technical expertise and wealth of resources within LabCorp to deliver greater value and more flexible solutions in helping our clients bring new medicines to market faster."
— David M. Johnston, Ph.D., senior vice president, global head, clinical trials

McCrone Associates, Inc.
Westmont, IL
www.mccroneassociates.com
(630) 887-7100

Key location: Westmont, IL
Contact: Dr. Kent Rhodes
analysis@mccrone.com

Main Service Areas: Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Services include non-routine, investigative microscopy and micro-analysis, including, but not limited to, product contaminant and material defect identification, quantification, and imaging. Capabilities include contaminant identification, materials characterization, compositional analysis, glass delamination analysis, particle counting, and particle size distribution.

"We are honored to be recognized as a leader in the categories of Productivity and Regulatory. This recognition is a testament to our staff's experience, technical skills, and resourceful approach to materials analysis and contaminant identification. We are committed to providing accurate results and the highest quality of service to all our clients."
— David Wiley, president and COO

Microbac Laboratories, Inc.
Pittsburgh, PA
www.microbac.com
(412) 459-1060

Key location: Wilson, NC
Contact: Robert Crookston
robert.crookston@microbac.com
Contact: Bill Rogers
bill.rogers@microbac.com

Main Service Areas: Pharmaceutical Testing

SERVICES & CAPABILITIES: Microbac offers analytical pharma testing and research services in support of the development, approval, and manufacture of pharmaceutical raw materials and finished products.

"It is an honor to be nominated and selected by Life Science Leader. Recognition of Microbac's position and leadership in the industry is something we are very proud of. The credit for this award goes to our scientists and laboratory support personnel. They strive to make a difference each and every day, and I'm very happy for them to be recognized for those efforts."
— James Nokes, president

MPI Research
Mattawan, MI
www.mpiresearch.com
(269) 668-3336

Key location: Mattawan, MI
Contact: Ed Amat, VP of global sales
ed.amat@mpiresearch.com

Main Service Areas: Bioanalytical, Preclinical

SERVICES & CAPABILITIES: General toxicology, infusion, DART, safety pharmacology, experimental therapeutics, neurobehavioral sciences, anatomic/clinical pathology, DMPK, *in vitro* service, *in vivo* models, imaging, medical device evaluation, antibiotic potency testing, bioanalytical analysis, immunology, dose formulation analysis, environmental and food safety testing, compound management

THERAPEUTIC AREAS: Cardiology, neurology, metabolic disease, orthopedic, endocrinology, oncology, ophthalmology, renal, inflammation/immune disorders, gastrointestinal, infectious disease

"Recognition in the productivity category reflects the depth of our scientific expertise and the wide ranging experience of our staff to meet the objectives of our sponsor programs. Responding quickly and thoughtfully when collaborating with our industry sponsors will remain a standard that our staff pride themselves on and work diligently towards every day, while maintaining the fundamental confidence our sponsors must have in our processes to assure that we meet and exceed the standards set by regulatory agencies worldwide."
— Tim Derrington, president and COO

OPTIVIA Biotechnology Inc.

Optivia Biotechnology Inc.
Menlo Park, CA
www.optiviabio.com
(650) 324-3177

Key locations: Menlo Park, CA
Contact: Dr. David Lustig
dlustig@optiviabio.com

Main Service Areas: Preclinical

SERVICES & CAPABILITIES: Comprehensive *in vitro* transporter assay services and custom transporter model development for drug interactions, DMPK, and toxicity studies.

THERAPEUTIC AREAS: All

"We are honored to receive this award as a validation of Optivia's scientific leadership in the rapidly growing transporter assay market. We are very pleased that our clients are satisfied with our services, and we will continue to provide them with more innovative, value-added transporter assay services and discovery solutions, supporting discovery and development of safer and more efficacious medicines."
— Yong Huang, Ph.D., president and CEO

PBL Pacific BioLabs
The Service Leader in Bioscience Testing

Pacific BioLabs
Hercules, CA
www.pacificbiolabs.com
(510) 964-9000

Key location: Hercules, CA
Contact: Aaron Burke
aaronburke@pacificbiolabs.com

Main Service Areas: Preclinical

SERVICES & CAPABILITIES: *In-vivo* toxicology, pharmacokinetics, radiolabeled ADME, cytotoxicity, biocompatibility, pyrogen testing, sterilization validations, sterility testing

THERAPEUTIC AREAS: Medical devices, pharmaceuticals, biotherapeutics

KEY INDUSTRY PARTNERS: Stryker, Johnson and Johnson, Mentor, ResMed, Dow, and GSK

"Pacific BioLabs strives to be The Service Leader in bioscience testing. Our people are able to deliver that service through constant diligence in understanding regulatory changes and in providing quality testing. PBL is honored to be recognized as a regulatory leader — it's a testament to the dedication and professionalism of all of our employees."
— Tom Spalding, president

PAREXEL
Right where you need us™

PAREXEL International
Waltham, MA
www.PAREXEL.com
(781) 487-9900

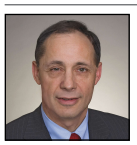
Key locations: Africa, America, Asia/Pacific Region, Europe, Middle East
Contact: Jennifer Baird
info@PAREXEL.com

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.

KEY INDUSTRY PARTNERS: PAREXEL serves the top 50 pharmaceutical companies, the top 10 global biotech companies, as well as hundreds of small and medium-sized biopharma companies. The company has also publicly announced strategic partnerships with BMS, GSK, Lilly, Merck, and Pfizer.



"For 30 years, PAREXEL has been a premier partner to clients that rely on the company for our expertise and the efficiencies of a worldwide infrastructure to achieve their development and commercialization goals. By partnering with PAREXEL, biopharmaceutical companies of all sizes can leverage our global resources and experience to improve early-stage decisions, reduce development timelines, maximize investments, and harness technologies to increase efficiency, quality, and safety — benefits that translate into marketplace advantages."
— Josef von Rickenbach, chairman and CEO

Pharmaceutical Product Development, LLC (PPD)
Wilmington, NC
www.ppdi.com
(910) 251-0081

Key locations: China, Scotland, United Kingdon, United States
Contact: Ned Glascock, associate director, corporate communications and public affairs
ppdinfo@ppdi.com

Main Service Areas: Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Clinical Development Services — Phase II-IIIb clinical studies; therapeutic and specialty expertise with dedicated project teams; post-approval services, including epidemiology; pharmacoepidemiology and health outcomes; risk management and REMS; safety surveillance studies; late stage studies; medical information; product safety; registries; and observational studies; clinical data management and information solutions, including consulting and proprietary software tools to speed collection, analysis, and reporting of clinical data; Laboratory Services — BioDuro, A PPD® Company; nonclinical development; preclinical services; Phase I clinic; GLP bioanalytical; cGMP product analysis; biomarker; vaccines and biologics, and Phase I-IV global central labs.

THERAPEUTIC AREAS: Cardiovascular, central nervous system, critical care, dermatology, endocrinology and metabolic studies, gastroenterology, hematology and oncology, immunology, infectious diseases, ophthalmology, pediatrics, respiratory, specialties, urology

KEY INDUSTRY PARTNERS: PPD has worked with all of the top 50 pharmaceutical* companies and 600+ biotechnology companies (* Ranked according to 2010 R&D spend)

PRA
Raleigh, NC
PH: (919) 786-8200
www.clearlypra.com

Key locations: Brazil, Canada, Germany, Netherlands, Singapore, United Kingdom, United States
Contact: Melissa Coloton
Colotonmelissa@PRAIntl.com

Main Service Areas: Bioanalytical, Clinical

SERVICES & CAPABILITIES: PRA provides a full suite of services, including Phase I – IIa studies, bioanalytical lab services, Phase II-III studies (with all supporting services), Phase IIIb, IV, and registry studies, and safety services.

THERAPEUTIC AREAS: PRA conducts studies across a variety of therapeutic areas and indications, with particular experience and expertise in oncology/hematology, neuroscience/CNS, cardiometabolic, infectious diseases, and respiratory/allergy.

KEY INDUSTRY PARTNERS: PRA has more than 45 different partnerships with more than 40 sponsors worldwide for a wide range of services ranging from specific functions to exclusive partnering for full outsourcing of clinical study programs.

"PRA's reliability results from an emphasis on quality and trust. These ideals are ingrained in our core values, evident in our culture and visible in our structure. Our global, cross-functional teams evaluate performance indicators and trend analysis with the goal to maintain reliable, high quality delivery to our clients. PRA's regulatory organization provides strategic consulting and serves our clients through an infrastructure of in-country regulatory experts supporting high quality local submissions and efficient global study start-up."
— Colin Shannon, president and CEO

Quantex Laboratories
Edison, NJ
www.quantexlabs.com
(732) 248-3335

Key location: Edison, New Jersey
Contact: Mary Oppel
Mary.oppel@quantexlabs.com

Main Service Areas: Bioanalytical, Preclinical

SERVICES & CAPABILITIES: Analytical development, method development, method validation, stability studies, impurity profiling, extractables and leachables, raw material qualification, residual solvents, release testing, materials characterization, GMP and CMC services

THERAPEUTIC AREAS: Allergy/immunology, cardiovascular, dermatology, dentistry/oral, gastrointestinal, infection control, inflammation, respiratory/pulmonary, orthopedic/skeletal, wound care, small molecule, large molecule, tablets, capsules, liquids, suspensions, injectables, stents, implantable devices, tissue

KEY INDUSTRY PARTNERS: J&J, Smith & Nephew, Ethicon, Vivimed, Colgate Palmolive, Proctor & Gamble

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"We are very honored and pleased to have been recognized as the leading CRO in the areas of productivity and regulatory compliance. We consider ourselves as partners in meeting the standards and goals set by our clients and regulators and in achieving high marks for compliance. As partners with our clients, our focus on productivity moves projects from concept to market, helping clients achieve developmental and marketing milestones in a timely and cost-effective manner."
— James Menoutis, president and CEO

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Quintiles
Durham, NC
www.quintiles.com
(919) 998-2000

Key locations: China, India, Japan, Singapore, United Kingdom, United States
Contact: Robin Wendlandt
robin.wendlandt@quintiles.com

Main Service Areas: Bioanalytical, Clinical

SERVICES & CAPABILITIES: Bioanalytical laboratories, biostatistics, biosimilars, central laboratories, clinical monitoring, data management, ECG, functional service provider, lifecycle safety, patient and investigator recruitment, medical writing, model-based drug development, regulatory, Quintiles Infosario.

THERAPEUTIC AREAS: Cardiovascular, central nervous system, endocrinology, infectious diseases, internal medicine, oncology, pediatrics, public health and government services, translational oncology, vaccines, women's health.

KEY INDUSTRY PARTNER: Cenduit

"We are honored to be recognized for our leadership in clinical research - which is ultimately about improving human health and saving lives. Quintiles employees worldwide are committed to developing new ways to improve the quality, reliability, and productivity of clinical research, helping speed the approval of new medicines for patients. Together with our customers, we're creating a new model of drug development that leverages expertise and data to make better decisions faster."
— Paula Brown Stafford, exec VP, clinical development

SCYNEXIS®

SCYNEXIS, Inc.
Research Triangle Park, NC
www.scynexis.com
(919) 544-8600

Key location: Research Triangle Park, NC
Contact: Terry Marquardt
terry.marquardt@scynexis.com

Main Service Areas: Bioanalytical, Preclinical

SERVICES & CAPABILITIES: SCYNEXIS delivers efficient and innovative drug discovery and development solutions to our global health and pharmaceutical partners through services that include integrated pharmaceutical solutions, discovery research, and integrated parasitology.

THERAPEUTIC AREAS: Anti-parasites, anti-infectives, CNS, ophthalmology, oncology, cardiovascular, and dermatology

KEY INDUSTRY PARTNERS: Merial Ltd., Medicines For Malaria Ventures, Drugs For Neglected Diseases initiative, Merck & Co., Mitsubishi Tanabe, Sanofi

"SCYNEXIS is recognized for its strict adherence to what we call the 'path to success', which starts with the definition of the customer's Target Product Profile at the start of each project, to define the path forward. We design workflows to meet the goals and define challenges and gaps, and then deploy a team with the right skills to render maximum progress in the project. SCYNEXIS works hard to deliver timely results to our customers."
— Dr. Yves Ribeill, president and CEO

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www.7thwavelabs.com
(636) 519-4885

Key locations: Chesterfield, MO; St. Louis, MO
Contact: Jody DeBold
info@7thwavelabs.com

Main Service Areas: Bioanalytical, Preclinical

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

THERAPEUTIC AREAS: We work across multiple therapeutic areas, including endocrinology and metabolic syndrome, cardiovascular, respiratory, inflammation in multiple organ systems, oncology, and neurology in support of a diversity of small organic and biotherapeutic compounds.

"We believe in putting the needs of our clients first, and we understand that time is money. Therefore, we respond quickly, and we remain flexible, allowing our clients to customize each project to meet their needs. Our multidisciplinary group of experts joins the sponsor as an extension of their internal team and dedicates themselves to each study as if it was their own."
— Dr. John Sagartz, CEO

SGS
Geneva, Switzerland
www.sgs.com/cro
41 22 739 91 11

Key locations: Belgium, Czech Republic, France, Poland, Spain, United Kingdom, United States
Contact: Frederic Gaussens
lss.info@sgs.com

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

KEY INDUSTRY PARTNERS: Oracle

"As the world's leading inspection, testing, certification, and verification company, SGS takes great pride in providing independent, high quality services across all the industries we serve, adhering to a strict code of integrity. We work hard to develop customized solutions for each of our clients to significantly improve their drug development timelines and decision-making processes. Each department from the clinical pharmacology group to project management, biometrics, and pharmacovigilance works together to exceed our client's expectations."
— Anne Hays, executive vice president, life science services

SIRO Clinpharm
Thane, Maharashtra India
www.siroclinpharm.com
91-22-2584-8000

Key locations: Czech Republic, Estonia, Germany, Greece, India, Malaysia, Romania, United States
Contact: Bruce Hardy
bd@siroclinpharm.com

Main Service Areas: Clinical

SERVICES & CAPABILITIES: Our subject expertise gives us an edge in clinical trial management, data management and medical writing, biostatistics, clinical trial supplies facility, medical services, and pharmacovigilance.

THERAPEUTIC AREAS: Oncology, diabetes, respiratory, cardiovascular, infectious diseases, vaccines

KEY INDUSTRY PARTNERS: Dream CIS (South Korea), VCRO (Taiwan)

"It is a pleasure to receive an award that represents the voice of the industry. The award in the quality, reliability, and regulatory aspects underscores what we at SIRO have always believed in — invest in quality people for quality delivery. This is an affirmation from our clients on our commitment to delivery."
— Gopakumar Menon, CEO

SSCI, a division of Aptuit
West Lafayette, IN
www.ssci-inc.com
(765) 463-0112

Key location: West Lafayette, IN
Contact: Pamela Smith
info@ssci-inc.com

Main Service Areas: Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Aptuit's solid state services: polymorphism, crystallization, salts, co-crystals, amorphous solids, patent prosecution and litigation, route and advanced analytical services, micrometrics, method development and validation, biochemistry, single crystal determination, indexing and short courses

THERAPEUTIC AREAS: Aptuit scientists offer drug development expertise across all therapeutic areas. Aptuit technical teams are comprised of scientific medical specialists who are focused on diseases and therapies that are driving the current market, including neuroscience, cardiovascular, oncology, and infectious disease.

KEY INDUSTRY PARTNERS: Aptuit partners with clients observing confidentiality in every aspect of our collaboration. Aptuit services more than 250 clients annually, including virtual; start-up; small, mid-size, and multinational pharmaceutical companies.

"SSCI, a division of Aptuit, is honored to be recognized for the superior quality of our scientific expertise in solid state chemistry and analytical research. We take great pride in our position as the industry leader in this crucial segment of drug development. As we move forward, we will continue to deliver scientific excellence to our clients by accelerating the pace at which they develop their products and improving the quality of the drugs that they provide to consumers around the world."
— Pamela A. Smith, Ph.D., senior director, site director

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Salt Lake City, UT
www.tandemlabs.com
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Key locations: Belgium, Canada, China, Germany, Singapore, United States
Contact: Todd Grosshandler
tlsales@labcorp.com

Main Service Areas: Bioanalytical

SERVICES & CAPABILITIES: GLP bioanalytical services, GLP biotechnology services, biomarkers, specialized LC-MS/MS, proteins, oligonucleotides, tissues, specialized biotechnology, immunogenicity, cell-based assays, alternative matrices

THERAPEUTIC AREAS: Laboratory services for all therapeutic areas

KEY INDUSTRY PARTNERS: LabCorp Clinical Trials, David H. Murdock Research Institute (DHMRI)

"Our ability to meet and exceed the expectations of our pharmaceutical clients is directly tied to the expertise and responsiveness of our staff. We focus exclusively on bioanalytical services from four sites across the United States, building strong relationships with clients that allow us to develop programs that meet even the most difficult challenges. We offer timely communications, structured method development for more rugged methods and improved ISR results, and reliable bioanalytical data."
— James K. Wilfahrt, vice president and general manager

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Bedford, MA
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(781) 275-3330

Key locations: Belgium, Europe
Contact: Mark DeSorbo
Mark.Desorbo@toxikon.com

Main Service Areas: Bioanalytical, Preclinical

SERVICES & CAPABILITIES: *In vivo* and *in vitro* studies, efficacy and surgical research, ocular drug development, synthesis and formulation, biocompatibility, full IND/NDA studies, analytical and bioanalytical, histology/pathology, PK/TK/ADME/DMPK, acute/subchronic/chronic genetic/reproductive toxicology, animal models

THERAPEUTIC AREAS: Including, but not limited, to cancer, neurodegenerative diseases, ocular (uveitis, glaucoma, dry eye, corneal, choroidial and retinal NV), arthritis, IBD, multiple sclerosis, dermatitis, diabetes, obesity, wound healing

KEY INDUSTRY PARTNERS: Biotech, pharma, medical device

"Drug and medical device companies have come to know Toxikon as a reliable partner who ensures that the products they develop are effective and safe. This award validates not only our commitment to being that reliable partner, but it also reinforces that life science companies know Toxikon provides the expertise and service they can depend on to see their product development through the regulatory process for timely market delivery."
— Dr. Laxman S. Desai, CEO

What Orphan Drugmakers Seek From CROs

By Roger Garceau

Regardless of size, CROs with the right mindset can flourish in specialty niches.

Many small and midsize CROs have struggled in the past few years as pharmaceutical companies slashed their research budgets. There's no question size and scale are a big plus for a CRO. However, smaller contract organizations that follow best practices and pay close heed to clients' needs can also be attractive partners in the fast-growing area of orphan drugs.

To seize the opportunities, it helps to understand the challenges orphan drugmakers face. Many of these players are themselves small companies working on just one or two products — each of them a one-off indication. In the case of NPS, which develops orphan therapies for GI and endocrine disorders, virtually all aspects of our preclinical and clinical studies must be outsourced, and finding the right partner is paramount.

Let's begin with the assets a large CRO brings to the table. First, they have breadth of experience, from writing protocols and handling toxicology in multiple animal models all the way to putting together advisory panels. Greater scale also means large players may be better prepared in a crisis. What happens, for example, if one of the CRO's trusted field monitors on a project quits or is taken out of commission mid-study? This can be catastrophic for the sponsor — especially for an orphan drugmaker that has groomed relationships with an academic research center, or a particular scientist or thought leader. A large CRO with a half dozen projects at the same research center is better positioned to substitute a competent monitor and transfer institutional knowledge.

SMALL CAN BE BEAUTIFUL

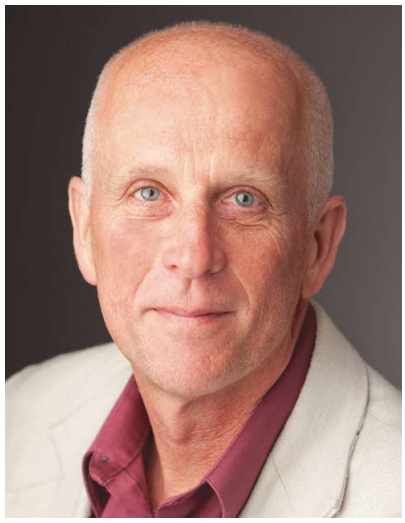
Acknowledging these large-company advantages, there are still aspects in which a small or midsize CRO has a fair chance, as long as it can provide certain assurances to the sponsor. For one thing, the CRO may have focused, specialized experience in the area being studied. In addition, the smaller client will have more clout with a CRO of comparable size than with a giant whose corporate culture closely mirrors that of Big Pharma. Such a client is bound to receive more personalized attention from a like-sized CRO.

Staff turnover also will probably be lower at a small CRO, sparing the client unnecessary interruptions and obstacles. By the same token, if a big contract organization is accustomed to dealing with Pfizer, Merck, or Novartis, it may not share the small drugmaker's sensitivity to time and budget constraints. A small to midsize CRO is more likely to recognize the immutable truth that time is money.

In summary, I see the following six core competencies for a CRO targeting the orphan space:

Track record. Even though each orphan drug is unique, clients want evidence that you have successfully tackled compounds or proteins resembling theirs. CROs should obtain permission from former clients to share success stories.

Performance metrics. For smaller specialty pharma, cost is key. The CRO should assign a project manager up front who can help the client keep costs under control in the face of unexpected delays or setbacks in the study.



Roger Garceau

Roger Garceau, MD, is senior VP and CMO of NPS Pharmaceuticals. He has more than 20 years of experience in the pharmaceutical industry.

Academic relationships. The CRO should show that it has experience in the timely resolution of contractual issues common in academic settings, e.g., disputes over intellectual property and publishing rights. Also, the CRO should prove that it can extract rigorous, consistent work from thought leaders who may have little experience with FDA registration studies.

Regulatory competence. As far as the FDA is concerned, the CRO is an extension of the sponsor. That means the client must own any mistakes the CRO makes. Every step of the process must be completely transparent to the client.

Honesty. Too many CROs roll out the A-team just once, during the initial meeting. Few deceits are worse than bait-and-switch. If you promise a client that you'll assign a particular study manager, don't back away from the commitment. Similarly, changing field monitors mid-study needs to be minimized.

Crisis Control. In the negotiating phase, the client must be assured that the CRO has fail-safes and backup plans if key personnel assigned to the project are suddenly put out of commission. Understand and compensate for liabilities related to your size.

The Business Of Equitable Research: The New Stakeholders

By James Gillespie and Kathleen Drennan

For an industry committed to delivering innovative healthcare, and where science outpaces antiquated trial planning and processes, there is no better time than now to take stock of the current burgeoning shift in population demographics and how it will affect the business of new drug development. But could it take another few decades to bridge the disparities gap of underrepresented patient populations in clinical trials compared to disease incidence — specifically Black/African Americans and Hispanic/Latinos, who will be the largest consumers of healthcare (2010 U.S. Census)? It took until the middle of the 1990s to acknowledge the lack of inclusion of women in clinical trials in any significant numbers, leaving a legacy of medicines extrapolated from studies done only in men. The industry missed opportunities to recognize critical scientific and gender issues affecting optimum treatments and outcomes in women's health, and it missed the biggest opportunity of all: Women are the largest buyers and decision makers of healthcare purchases.

A COMPLEX CHALLENGE AND STRONG CALL TO ACTION

The FDA is rapidly pushing the current diversity agenda of reducing disparity between disease incidence and prevalence in minority populations and the sample size represented in clinical trials. The FDA established the Office of Minority Health in 2010 to advance the Agency's regulatory oversight in achieving the highest standard of health for all.

Is industry, including CROs, giving adequate attention and proactive planning to guidelines and suggestions, which will surely become an issue at the time of FDA scrutiny, of their clinical trials and new drug approval? How many companies are addressing and including "multicultural competency" across their research endeavors necessary to make progress?

What is cultural competence as it relates to developing new medicines through clinical trials for the three primary stakeholders as guided by the FDA?

- *For industry,* it is a set of congruent behaviors, attitudes, and policies coming together in a system, agency, or among professionals enabling those entities to understand and work effectively in cross-cultural situations.
- *For clinical sites,* it is culturally competent physicians and study coordinators providing patient-centered care by adjusting attitudes and behaviors to account for the impact of emotional, cultural, social, and psychological issues on the disease.
- *For patients,* culture is a set of behaviors taught and inherited as members of a particular group, guiding how to view the world and healthcare, how to experience it emotionally, and how to behave in relation to other people and their disease.

James Gillespie

James Gillespie, Ph.D., J.D., M.P.A., is president of the Center for Healthcare Innovation, president of the National Biotechnology & Pharmaceutical Association, and president of the National Hispanic Life Science Society.

Kathleen Drennan

Kathleen Drennan is founding president and CEO of TrialAdvance, Inc., established to bring real-world insights of patients and trial sites to the relevant planning, execution, and management of clinical trials.

Racial and ethnic segmentation strategies demand a departure from business-as-usual in the development of clinical trials, especially when envisioning trial-site communications, patient education materials, and doctor/patient relationships. New mindsets and skills are needed to address long-entrenched patient skepticism and deeply rooted mistrust about the accuracy of healthcare information, medical institutions, and especially the industry itself.

THE STAKES ARE HIGH

In 2011, the FDA approved the first new drug to treat lupus in 56 years. Lupus disproportionately affects women, and usually develops between ages 15 and 44. Estimates vary on the number of lupus sufferers in the United States, ranging from approximately 300,000 to 1.5 million people. People of all races can have the disease; however, African American women have a three times higher incidence (number of new cases) than Caucasian women. Two clinical studies with lupus demonstrated the safety and effectiveness of the drug, but patients of African heritage participating in the two studies did not appear to respond to treatment. The studies lacked sufficient numbers to establish a definite conclusion, so the sponsor agreed to conduct an additional study of people with those backgrounds to further evaluate the safety and effectiveness of this lupus drug.

This is a recurring story suggesting that proactive planning of such protocols could eliminate having to go back and do additional studies. The most dramatic of examples is the incidence of diabetes in the United States versus adequate study enrollment representation. Looking at published data readily available from many sources on the Internet, diabetes affects over 60% underrepresented populations, whereas enrollment of such populations in clinical trials averages about 11% or less.

> There is no better time than now to take stock of the current burgeoning shift in population demographics and how it will affect the business of new drug development.

The ability to reach and motivate patient communities representing populations needed to participate in today's clinical trials is not insurmountable; however, it is challenging. Progressive and enlightened companies that embrace clinical trial diversity as an integral part of their research planning and processes will build new bridges with the patient and physician communities. Adopting a multicultural competence methodology at the clinical-team level must include aggressive strategy and investment deviating from the current norm.

7 Ways To Manage Liability Risks For A CRO

By Kevin Quinley

Springtime brings March Madness and the college basketball championships. No championship trophy awaits top CROs, but the fruits of victory will go to CROs that build strong risk management systems and that have financial protection against liability claims. Amid increasing litigation, CROs face liability claims and lawsuits from subjects who assert injury due to a clinical trial going awry. To protect themselves, CROs need the safety net of liability insurance coverage.

To get the best deal on liability insurance coverage, CROs must demonstrate the presence of sound risk management programs. Insurance underwriters are the gatekeepers who decide on the availability and cost of CRO insurance coverage. They may demand substantial information for their risk assessment process. CROs that can showcase strong safety programs can "sell" themselves as a desirable risk and leverage the best deal for financial protection. Here, the best deal means the broadest insurance coverage at the lowest cost.

What will underwriters look for? What risk management features can CROs spotlight to position themselves in the best light? Here are seven factors to consider:

1. Informed consents. Have these reviewed by legal counsel to ensure they are clear and comprehensive. Beyond the wording and drafting, the process of presenting informed consent forms to subjects must be informative and elicit consent. Those delivering informed consents to subjects must be properly trained. Informed consents cannot be too brief or too detailed. If they are too short, plaintiff attorneys will argue that you cut corners. If they are too detailed, the same attorneys will claim you drowned out the true message in a sea of minutiae. It is a balancing act. Further, informed consents should avoid technical, legal, and medical jargon that most subjects will not understand. With the growing prevalence of clinical trials in international settings, translations of informed consents are crucial to ensure that risks and potential benefits are clearly communicated.

2. Patient recruitment practices. CROs must see that patient recruitment processes are bulletproof. In court, plaintiff attorneys will try to portray a process that plays fast and loose with patients, taking in subjects that do not fit the profile needed in order to "hit the numbers" or to gain recruitment bonuses.

3. Quality investigators. Astute underwriters may probe the following aspects:

Have you selected qualified physicians to fulfill the investigator roles?

When you identify noncompliance incidents, do you take prompt action?

Does the CRO stop using investigators with known compliance issues and avoid using those with prior "baggage?"

Does the CRO thoroughly vet investigators and conduct due diligence in selecting them?

4. Clear roles and responsibilities. Clinical trial outsourcing is a growing phenomenon. This fact makes it critical for CROs to outline all roles and responsibilities in their agreements with other parties. If an adverse outcome arises, the division of labor codified in documentation may become crucial. In serious situations, it may not be immediately clear how something happened or who is responsible. Responses in addressing adverse subject outcomes must be collaborative. Insurers underwriting CROs will seek clarity in contracts spelling out just what the role of the CRO is and is not.

5. Claims history. Has the CRO had any prior liability claims or lawsuits? If so, what did they cost? Were any litigated to conclusion or were they settled? How recent or aged are the closed claims?

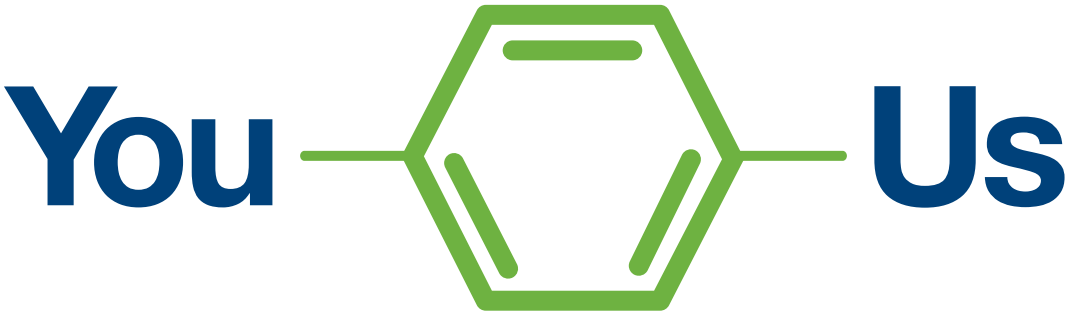
6. Regulatory baggage. What has been the relationship between the CRO and the FDA? Have there been any regulatory actions against the CRO?

7. Risk management infrastructure. Does the company have a full-time risk manager? Does the CRO view adherence to FDA guidelines as the "end all and be all" of risk management or realize that meeting FDA guidelines represents merely a floor, not a ceiling?

Savvy CRO managers and executives will put themselves in the shoes of insurance underwriters and ponder the features that go into differentiating good risks from poor risks. Using these considerations as specifications in building your risk management program will yield dividends in the form of lower costs and broader coverage for financial protection.

Kevin Quinley

Kevin Quinley is a risk management specialist and principal of Quinley Risk Associates, LLC, Fairfax, VA.



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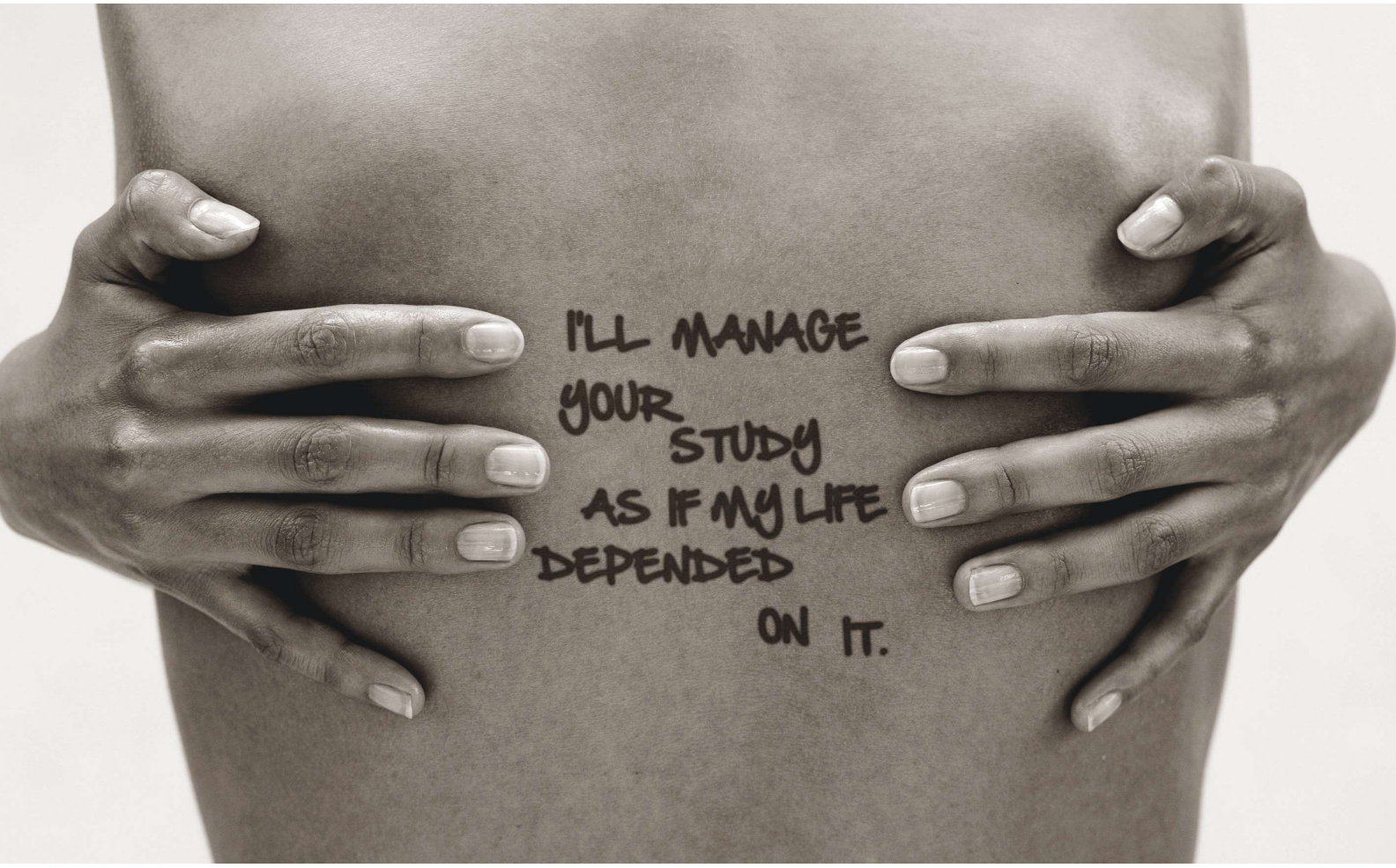

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