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SPECIAL ISSUE: THE CRO LEADERSHIP AWARDS

Whom have your peers chosen as the best?

CROs: Functional vs. Full Service p. 18

Risk-Based Monitoring: All Talk And No Action p. 32

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R&D costs per NME (new molecular entity) are increasing at exponential rates. When you consider a pharma company's R&D spend in a year, and divide that by the number of drugs approved, you obtain clarity on the skyrocketing cost for successful drug discovery. In a November 2012 presentation, Novartis Global Head of Development, Timothy Wright, M.D., estimated his company's R&D costs for the 21 recently approved drugs to average a stunning $3.9 billion per new drug. This may seem high, but is well below the industry average of $5.2 billion. When comparing Novartis' numbers to its top 10 pharma peers, they look really good, having the lowest cost per drug. Merck is fairly close at $4.2 billion per drug (16 approvals in 2012), while AstraZeneca is in the stratosphere, averaging a staggering $11.7 billion for its five approvals. Obviously, these spending levels are not sustainable. A revolution in the clinical trial space is needed — desperately — and CROs play a key role with all sizes of pharmaceutical and biotech companies. For example, when Pfizer announced in 2011 the reduction from 17 functional clinical research providers to two strategic partnerships with ICON and PAREXEL, it was clear the company no longer viewed CROs as merely excess research capacity. Pfizer's aim was to provide its strategic partners with a "significant" amount of work, make them more accountable for results, with the desired result being increased productivity. At the opposite end of the spectrum are virtual drug development organizations, such as Sensor Pharmaceuticals. Jim Hauske, president and founder of Sensor, says, "It's important to appreciate in my present capacity, that *all* experiments, data acquisition, and all FDA-required information, guidance/meetings, consultations, and submissions are outsourced. Over the 8-plus years I was senior VP of drug discovery at Sepracor, I did have many occasions requiring an insource versus an outsource decision. However, I outsource everything now." Because outsourcers play such a vital role to the pharma/biopharm industry, Life Science Leader magazine developed the CRO Leadership Awards, which are determined through customer data analysis via an independent market research organization. CROs that rank in the top 20% for innovation, productivity, quality, regulatory, and reliability are CRO Leadership Award winners for that category. Life Science Leader would like to congratulate all of this year's CRO Leadership Award winners, and recognize them for the important role they play in continuing to revolutionize clinical trials.

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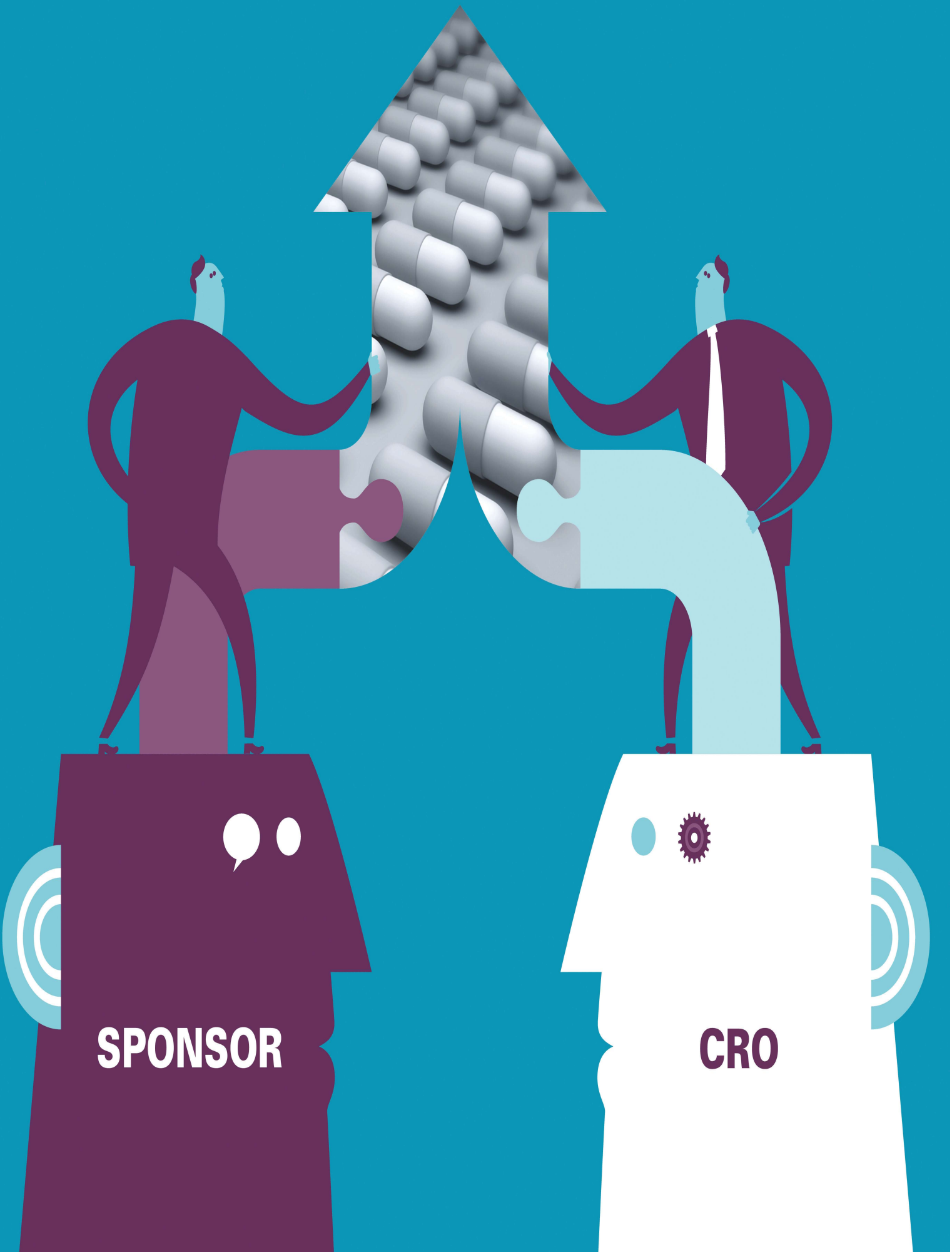
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CRO

Executive Roundtable:

Make Your CRO A True Extension Of Your Internal Team

By Rob Wright

In May 2011, Pfizer announced it would reduce its clinical research functional service providers from 17 to 2. Initially, this 88% reduction seemed to contradict the trend of pharma and biopharma to increasingly outsource clinical research. That year, the global healthcare contract research outsourcing market was valued at $25.1 billion. By 2018, the market is forecast to reach $65 billion. How can the clinical research market be growing, when companies like Pfizer are employing fewer organizations? Simple. The move on the part of Pfizer is representative of the growing trend of strategic partnering — putting more of your research eggs into fewer CRO research baskets.

ROUNDTABLE PARTICIPANTS

Dr. Kenneth Burhop, chief scientific officer, Sangart

Carolyn Green, president and director, Atreaon

Jim Hauske, president and founder, Sensor Pharmaceuticals

John Hubbard, senior VP and worldwide head of development operations, Pfizer

Mitch Katz, executive director of medical research operations, Purdue Pharma

Mary Rose Keller, VP of clinical operations, Sangart

Thomas Wessel, M.D., Ph.D, consultant and former CMO, Acorda Therapeutics, Inc.

Leslie Williams, president, CEO, and founder, ImmusanT

According to John Hubbard, senior VP and worldwide head of development operations for Pfizer, the move to partner with fewer CROs was intended to provide the company's collaborators with a significant volume of work on which to focus their attention, thereby increasing their accountability and, hopefully, their productivity. "The industry as a whole had been very capital-intensive in terms of the amount of money spent versus each dollar received," stated Hubbard. "We thought we should be able to get a higher efficiency against the amount of capital we spent."

The pharmaceutical industry had one of its most productive years in 2012, with 39 FDA approvals. But the improved productivity came at a very high cost. Novartis for example, estimates the company's R&D costs to average $3.9 billion per new drug, which is obviously not sustainable. Companies are seeking a variety of means with which to reduce costs, while increasing productivity. CROs are playing an ever-increasingly important role. But outsourcing your clinical research, and placing more projects with fewer providers, entail greater risk. To discuss that theme, *Life Science Leader* reached out to eight industry experts to gain their insights. Their expertise ranges from virtual biotech up to and including the largest pharmaceutical company in the world. Armed with their wisdom, you should be better equipped in developing CRO strategic partnerships — whereby the CRO functions as a true extension of your internal team. The panel includes Dr. Kenneth Burhop, chief scientific officer, Sangart; Carolyn Green, president and director, Atreaon; Jim Hauske, president and founder, Sensor Pharmaceuticals; John Hubbard, senior VP and worldwide head of development operations, Pfizer; Mitch Katz, executive director of medical research operations, Purdue Pharma; Mary Rose Keller, VP of clinical operations, Sangart; Thomas Wessel, M.D., Ph.D, consultant and former chief medical officer, Acorda Therapeutics, Inc.; and Leslie Williams, president, CEO, and founder, ImmusanT.

WHAT IS THE BIGGEST NEGATIVE PERCEPTION CROs SHOULD WORK TO OVERCOME?

Carolyn Green, Atreaon: Smaller companies need to assure their clients that their facilities have a level of quality that ensures the work is well-controlled, repeatable, and documented in a sufficiently detailed and timely manner. This is necessary to overcome the perception that non-Good "X" Practice facilities, (i.e. GMP, GLP, GCP) are "free-for-alls" with little control and no layers of oversight. Take the time to explain what you do to ensure the quality of your work and the accuracy of your data. Large CROs need to overcome the perception held by small venture-backed firms that because we are small, and only have only a few projects, we might not get the same time and attention as larger firms with more projects. Large CROs need to demonstrate that the teams responsible for all the great data of the past are still around. Otherwise, you are wondering if you are getting new recruits who have never run a particular model before.

John Hubbard, Pfizer: All CROs should seek to understand their customer product portfolios, needs, and challenges. They need to move away from transactional selling of services to a more solution-based approach. Many CRO teams still ask the sponsor "tell me what you want" as opposed to providing options and alternatives to the challenges we face in managing our clinical development portfolios. CRO leadership needs to invest in the education of their teams regarding the changing philosophy of outsourcing, and what it means to the way they work and interface with sponsors. There is still a disconnect in all large CROs that creates unnecessary friction as teams learn to work together. Change management training needs to occur in the sponsor organizations as roles shift from being "doers" to subject-matter experts, area leaders, and project managers. Encourage open communication, set clear expectations, and build trust within these virtual teams.

CROs help Pharmaceutical companies manage clinical trials.

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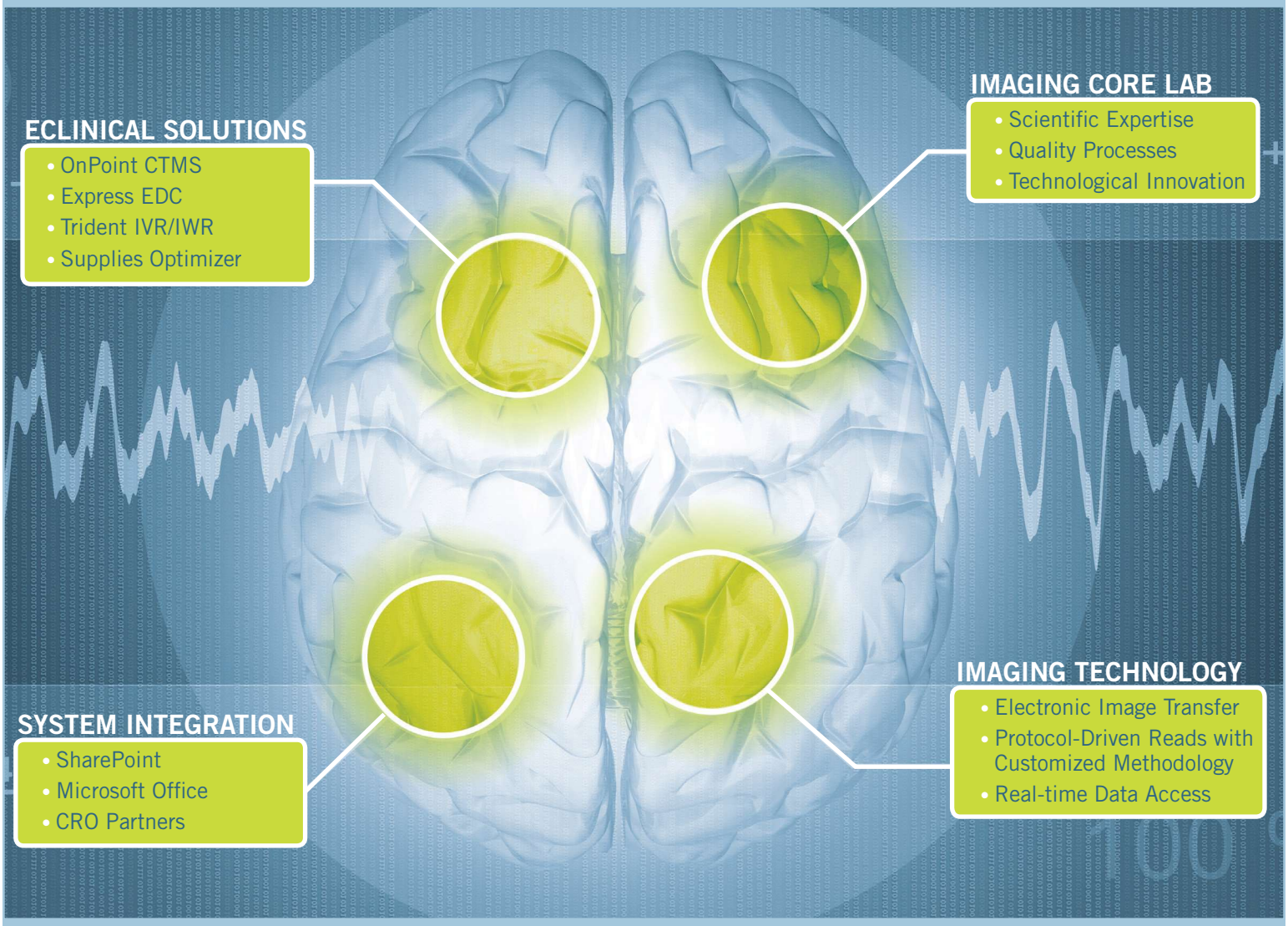

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Mary Rose Keller, Sangart: Commodification of clinical research is not attractive to R&D colleagues. It suggests that success lies in faster and cheaper, not in better outcomes for patients or investors. Bid defense should be more about how the CRO approach will deliver quality data to define a clear outcome than reviewing hundreds of lines of cost detail. Metrics are important, but how they are achieved is more important. Keep the messages simple. If you can draw your study management organization on the back of a napkin in the lobby of the hotel, you can probably run my study.

DESCRIBE A SITUATION WHEN YOU WISH YOU HAD OUTSOURCED SOONER AND WHY?

Green: I can share a time when I wish we had switched vendors sooner. We were working with a small non-GMP protein manufacturer to take a university manufacturing process from the first small-scale validation of the process through to making the first material. As the lots grew slightly larger, the material was tending to be more insoluble, and therefore, would require the expertise of a team with experience in removing proteins from inclusion bodies. The vendor didn't have that expertise. A mistake can occur when work shifts and the focus moves outside the vendor's level of expertise.

Mitch Katz, Purdue Pharma L.P.: While implementing certain development plans, I have needed to work sequentially. If I had utilized outsourcing, much of the work could have been performed at the same time, thus resulting in the earlier (and potentially less stressful) completion of the entire project.

Keller: In a previous company, we needed to conduct a very simple classical Phase 3 study in a common condition. At the same time, we were going to start a new program with the same

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compound in a much more complex area. We assumed because the Phase 3 study was so straightforward, the team could manage both activities at the same time. It was foolish to think that any study is straightforward if people aren't 100% focused on it. By the time we outsourced it, the study was classified by the lucky CRO that won the bid as a "rescue."

Jim Hauske, Sensor Pharmaceuticals: I always wished I had outsourced sooner. If the program is successful, the success would have been seen at an earlier date, and this impacts IP protection. For those failed programs, outsourcing sooner will define the failure more quickly and ultimately save money. It will also focus your attention on the next program and, hopefully, a more successful program.

Thomas Wessel, M.D., Ph.D, Consultant: We attempted to recruit all patients for a small, special pharmacokinetic study at a single academic center. When it became clear that this center could not deliver the number of patients needed within a given timeframe, we decided to work with a CRO that had experience in this area and to search for other qualified centers. The process of identifying additional sites, negotiating contracts, and bringing other centers "online" would have better been performed by a CRO from the beginning.

DESCRIBE A SITUATION WHERE YOU REGRETTED OUTSOURCING CLINICAL RESEARCH AND WHY?

Green: The situations where we regretted working with a CRO typically have come when expectations were not set, or at least were not properly set, at the beginning of the relationship. Contract research labs would be wise not to overstate their capabilities just to get the contract. We prefer when a lab is up front with us about what they are good at, and what they prefer not to do. Conversely, we find it is helpful to set the vendor's expectations on what we are looking for in terms of timing, communication. and written reporting. Our approach to outsourcing can be very hands-on and rather demanding of data, which is not easy for some CROs to deal with, especially if their internal processes are a one-size-fits-all approach.

Katz: I outsourced a very complicated project that required a great deal of training, hand-holding, and explanation. It might have been wiser to have insourced the project.

Keller: I selected a CRO that had a good reputation that I had used recently with a good outcome. I did not fully appreciate the CRO had made some significant internal organizational changes following a large acquisition, which changed the interface between sponsor and sites. As a result, we had many early misunderstandings on how to work together. When we finally determined we needed a reset meeting to revisit responsibilities and delegation of tasks, we came to the realization that the revised CRO working model no longer aligned with our needs or way of working with investigators. Failure to assess how the work will be done is every bit as important as assessing capability and experience.

Wessel: On one occasion, we were disappointed in CRO performance because the initially assigned (and highly competent) monitoring team was migrating to another project. Missteps like that can be prevented if recognized early and corrected through communication and collaborative problem solving.

WHEN DO YOU FEEL IT IS MOST APPROPRIATE TO OUTSOURCE PRECLINICAL/ CLINICAL RESEARCH?

Dr. Kenneth Burhop, Sangart: When the study falls into the general category of "routine" (i.e. we do not

Big Pharma Sees Benefits To Outsourcing Pre/Clinical Research

According to John Hubbard, senior VP and worldwide head of development operations for Pfizer, there are a number of benefits to clinical outsourcing. "The primary advantage to outsourcing your clinical and preclinical work is the ability to convert your fixed to variable costs. The biopharmaceutical industry has a fairly high cost of capital due to significant fixed infrastructure costs. As the industry seeks to manage the revenue decline from the loss of exclusivity, many companies are closing R&D sites, desupporting legacy IT systems, and reducing geographic footprint.

"Whether you take a staff augmentation approach or utilize a strategic alliance model, outsourcing provides the biopharmaceutical company with flexibility and the ability to leverage infrastructure during this time of change. In addition, as many large biopharmaceutical companies are re-evaluating their geographic footprint for conducting clinical trials, CROs offer the ability to maintain a presence in-country using a more flexible model. In many cases, large global CROs have a more established presence in some countries, which allows the biopharmaceutical company to establish an above-country model to operate as a hub working with the CRO partners that have operations in those countries. Finally, some CROs offer specialized services that can't or are not cost effective to replicate in a biopharmaceutical or biotech company. Some examples are rater training, interactive voice response services, and imaging services. As the industry becomes more virtual, the need to critically assess internal and external capabilities for cost effectiveness becomes a critical component of your overall development strategy."

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want to hire and expend valuable internal expertise and money on conducting studies that are common, labor intensive, time consuming, and that require expensive instrumentation that is only utilized occasionally) and when studies require Good Laboratory Practice (GLP) conduct (i.e. it is too costly for us to get involved with all of the quality systems and operations and technical support required to conduct true GLP research). We do not want to have on staff dedicated pathologists, laboratory animal handlers, specialized clinical laboratory chemists, etc., and we can't possibly afford the vivarium costs or equipment costs to conduct all research in-house.

Katz: When you have a small internal staff and there are restrictions to hiring more staff, when the CRO has particular expertise suited to the project, when the project is in an early stage, or when the CRO is a trusted partner.

Leslie Williams, ImmusanT: When there are noncritical aspects or "programmed" aspects of pre/clinical research. When the company lacks infrastructure and/or expertise, it is important to outsource. I am more apt to consider outsourcing if face-to-face meetings can be scheduled easily – thus "locality" of provider is a consideration.

WHAT METRICS DO YOU USE TO DETERMINE IF YOU SHOULD OUTSOURCE PRE/CLINICAL RESEARCH?

Burhop: Our primary metrics are cost and need. It is relatively easy for us to determine if it makes financial sense for us to outsource (e.g. conduct parallel studies, conduct studies requiring a large number of resources like repeat-dose toxicity testing, and if it requires capabilities we don't have in-house, such as animal handling capabilities for primates or unique and expensive laboratory equipment).

Hauske: Expense is usually the chief metric. However, on the clinical development side, experience dealing with the FDA (particularly in terms of the specific disease section, FDA expert, decision makers, key opinion leaders) is *the* determinant for my choice of clinical development partner. Unfortunately, in my experience, one pays a significant premium to access outsourcing providers with this sort of staff. Be willing to pay a premium since success in the clinic more than offsets budget overruns.

Wessel: It is important to accurately assess the sponsor's capacity to initiate and sustain a given project over time. For this purpose, mapping out individual steps in project execution, assessing the needs for existing or future headcount, assigning accountability, and defining timelines are essential. In my experience, it is a great advantage to have a team member with project management and budgetary authority to monitor progress and change course quickly if necessary.

CRO Selection Is Personal, Not Just Business

"We must always keep in mind the people we choose to join our teams are the single most important reason we succeed or fail," says Jim Hauske, president and founder of Sensor Pharmaceuticals. "Although this is true for all discovery and development programs whether insourced or outsourced, it's particularly important to know the individuals in the company you select to place your outsourced program." Hauske advises you to focus on developing deep, personal business relationships with the outsourced management team, as well as those members of the outsourced team actually performing the work. Here's why.

"As a virtual company, it is actually relatively easy to assess companies and, most importantly, people with apparently appropriate experience to perform critical experiments," affirms Hauske. During his 25 years of pharma "brick and mortar" experience, Hauske observed the Jack Welch (former CEO of GE) approach to management applied to R&D team performance assessments, whereby teams considered to be the trailing 10% were summarily fired every year. He asserts that these teams consisted of top talent, as well as poor performers, and both have found their way into CROs. "There are members of even the best drug discovery and drug development pharmaceutical organizations you would not trust to perform your critical experiments," he says. "You must know the person who performs your experiment. It is no different from managing an insourced team. Take pains to assess true competency. Despite your best efforts, in some cases, a poor choice of service provider will be made. The best way to minimize such an undesirable result is to develop strong personal relationships with a number of individuals within the organization, especially those most responsible for creating the corporate culture. When something goes astray, and something always does, you need to have strong personal connections to expeditiously get things back on track without causing pain to those actually performing the work."

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WHAT SPECIFIC ADVICE DO YOU HAVE FOR EXECUTIVES INVOLVED IN THE INSOURCING VERSUS OUTSOURCING DECISION?

Burhop: The key to outsourcing preclinical studies is to conduct solid and extensive up-front research on each CRO under consideration for a particular study. Go with the company that genuinely cares about your product development and is willing to work with you as a partner versus just another customer bringing in money. Reputation and scientific expertise, combined with quality and timely output, are key. In the end, much of this is about establishing a relationship with a CRO and, in particular, with the study director assigned to your study. They have to be extensions of your internal team. Consider all of the trade-offs of cost relative to lost time, training of resources, ongoing need for special resources, talent, and ultimately the quality of the work.

Hubbard: We are moving into an era where "transactional" insourcing of personnel to support projects, or outsourcing of full programs to CROs needs to be part of a more integrated and overall drug development strategy. Fiscal pressure on both sponsors and CROs continues, while the need to improve quality and enhance delivery and competitiveness cause opposing pressures. The solution is to apply a more strategic approach. For example, specific technical, operational, or regional capabilities can be accessed using CROs without building internal infrastructure. This is highly useful when new product is acquired through licensing or via an acquisition, thus maintaining a high degree of flexibility for noncore areas. A more long-term perspective allows organizations to learn and grow together, significantly reducing the cost of sales and overhead within the sponsor organizations, improving staff utilization, and reducing operating expenses overall. It also provides a foundation for joint innovation which can be shared by both organizations. The solution needs to be fully accepted throughout the sponsor and CRO organizations, since it may create constraints on the number of providers to be utilized — virtually eliminating the traditional Request for Proposal, RFP, and Request for Information, RFI, processes.

Williams: It is vital to determine early on the critical proprietary aspects of the program and build those within your organization. Outsource only noncritical or "programmed" aspects of your program. Continually assess/reassess and determine what critical initiatives may need parallel tracks.

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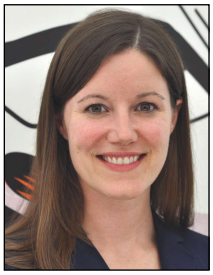


OUTSOURCING INSIGHTS

Strategic Outsourcing Often Means Combining Functional and Full-Service CROs

By Kate Hammeke, director of marketing intelligence, Nice Insight

If you're in the business of drug development as an innovator, chances are outsourcing has become part of your strategy. Engaging outside firms to complete one or more of the steps necessary to bring a new medicine to market has been proven to add value to the process by reducing fixed costs, shortening timelines and offering access to niche expertise. With outsourcing becoming so integral to drug development strategy, the term "strategic" can be applied to almost any method of engaging outside providers, whether it is for a single element of the process or multiple steps along the way.

There are advantages and drawbacks to each outsourcing approach, and many subcontracting relationships fall somewhere between a one-off job and a one-stop shop. The decision of whether to engage functional service providers for tactical needs or a full-service provider that can assist with a broader range of activities can only come through evaluating the needs for a specific project, coupled with the long-term needs and goals of the sponsor organization. However, understanding some benefits and disadvantages for each — in addition to learning what has worked for similar businesses — can offer insight into which practices will bring the most value to your firm.

Functional or specialty CROs tend to offer a limited range of services and have expertise in a specific therapeutic area, methodology, or service. These companies may be local or global, and they add value to sponsor organizations through access to expertise while at the same time retaining control over the process. They tend to be more flexible and have the ability to quickly respond to client needs. However, they have their limits when it comes to capabilities and capacity. Functional outsourcing can present challenges to sponsor organizations with respect to identifying the best specialty provider and in stretching resources to manage multiple providers.

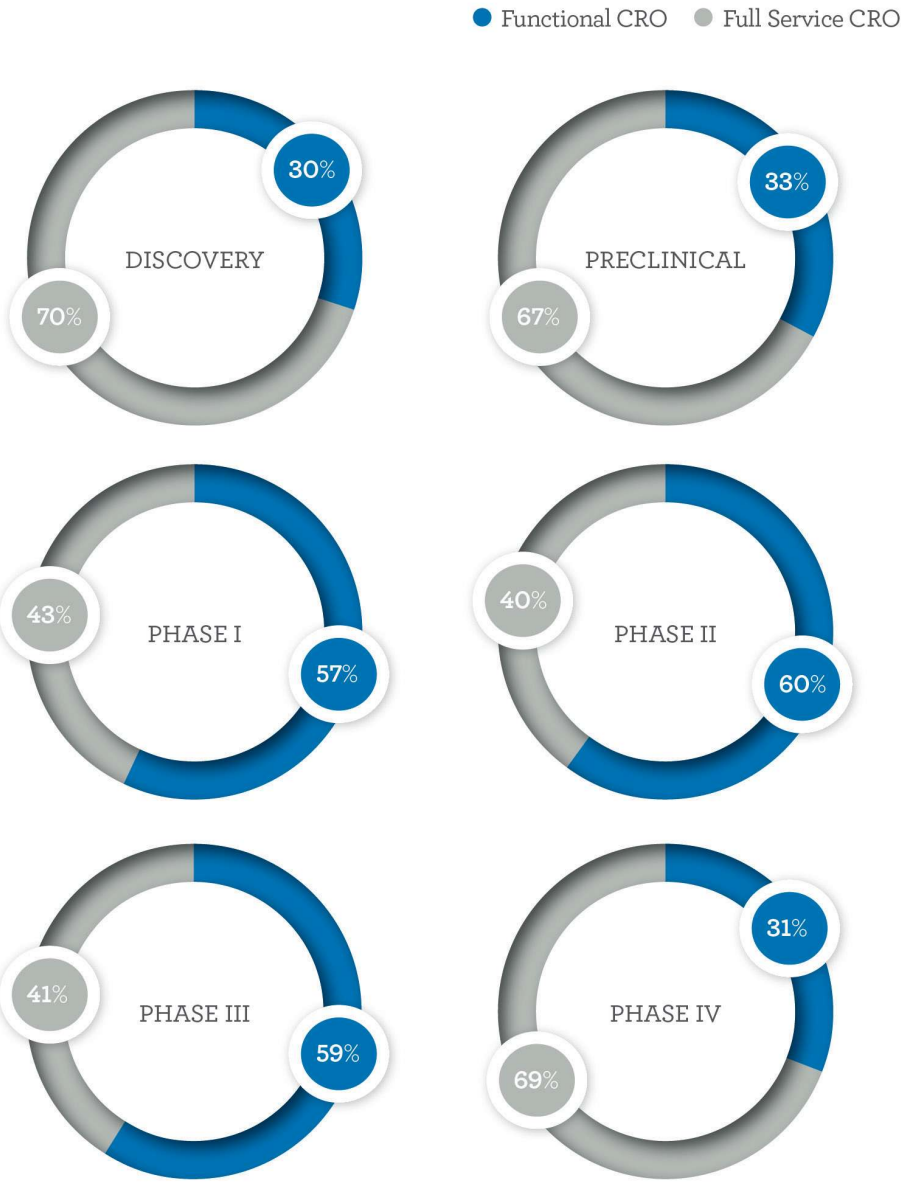
Full-service CROs offer a complete range of services from preclinical development through to marketing. They enable a sponsor organization to have a single point of contact for multiple outsourced needs, which can reduce the expenses associated with identifying and vetting a CRO and the resources allocated to managing multiple vendors. It also minimizes frustrations related to miscommunication, misunderstood priorities, and delays associated with decision making. On the flip side, a full-service CRO may comprise disparate business units scattered across the globe with no guarantee of integration or communication across locations and cultures, despite standing as one brand. This can obviously nullify the inherent benefit.

Nice Insight research has shown outsourcing preferences frequently vary across different buyer groups, and the inclination to use one outsourcing method over another is no exception. As a matter of fact, not only does the preferred method vary by sponsor category, the decision to use a functional or full-service CRO is heavily influenced by the phase of development. With the exception of Big Pharma — who display parity interest in using full-service or functional CROs — respondents show a strong preference towards engaging a full-service CRO for Discovery phase projects (70%). This is also true of preclinical phase outsourcing, where 67% of respondents indicated a preference for a full-service CRO, yet Big Pharma preferences remain even.

However, there is a distinct shift in preference when transitioning from preclinical to clinical development phases. More than half (57%) of respondents prefer a functional CRO for Phase I trials. The inclination to use a specialty CRO rather than a full-service CRO remains true for Phase II (60%) and Phase III (59%) trials, perhaps driven by small and midsize pharma companies needs, since biotech companies show an even interest in specialty and full-service CROs for Phase I-III trials. Interestingly, Big Pharma demonstrates a preference towards full-service CROs for clinical trials. This may tie back to the increasing complexity of Phase I trials, where small or midsize pharma companies seek out specialty CROs to gain access to expertise while Big Pharma companies' internal expertise can assist in surmounting any challenges a full-service CRO encounters. The preference for full-service CROs reemerges at Phase IV (69%), and it is the only phase where a majority of respondents from each sponsor category show partiality towards full-service providers.

Deciding on whether your strategy involves the use of several functional CROs or a full-service CRO to address multiple needs won't always be clear-cut. But learning from the experiences of your peers — as well as considering future goals and needs — can help with more informed strategic decisions to address present needs.

Functional vs Full-Service CRO Preference by Phase of Development



Survey Methodology: The Nice Insight Pharmaceutical and Biotechnology Survey is deployed to outsourcing-facing pharmaceutical and biotechnology executives on an annual basis. The 2012 sample size is 10,036 respondents. The survey is composed of 500+ questions and randomly presents ~30 questions to each respondent in order to collect baseline information with respect to customer awareness and customer perceptions on 170 companies that service the drug development cycle. Over 800 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, Innovation, Regulatory Track Record, Affordability, Productivity, and Reliability.


Walker

If you want to learn more about the report or about how to participate, please contact Nigel Walker, managing director, or Salvatore Fazzolari, director of client services, at Nice Insight by sending an email to niceinsight.survey@thatsnice.com.

THE CRO LEADERSHIP AWARDS 2013

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Covance Inc.
Eurofins Lancaster Laboratories, Inc.
Harlan Laboratories Inc
Impact Analytical
INC Research
inVentiv Health Clinical
Product Safety Labs
Seventh Wave Laboratories
Toxikon Corporation

THE CRO LEADERSHIP AWARDS PRODUCTIVITY AWARD

Agilux Laboratories
Chiltern
Comprehensive Clinical Development
Covance Inc.
Eurofins Lancaster Laboratories, Inc.
Harlan Laboratories Inc
Impact Analytical
Jubilant Clinsys Inc.
MPI Research
PAREXEL International
PPD
Quintiles
Rho
SCYNEXIS

THE CRO LEADERSHIP AWARDS INNOVATION AWARD

Agilux Laboratories
BASi
Charles River
Chiltern
Covance Inc.
Eurofins Lancaster Laboratories, Inc.
Impact Analytical
INC Research
Quanticate
Quintiles
SCYNEXIS
Seventh Wave Laboratories
Toxikon Corporation

ABC (Analytical Bio-Chemistry) Laboratories, Inc. • Columbia, MO
www.abclabs.com • (888) 222-4331
key locations: Columbia, MO and Sacramento, CA
contact: Kristein King • kingk@abclabs.com

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical, Clinical (Phase 1, Phase 2, and Phase 3)
Formulated Drug Production: Dosage Form Development

Main Service Areas:
Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Full CMC support for large and small molecule programs including method development & validation, characterization, extractables & leachables, stability services, quality control testing, plus bioanalytical services, radiolabeling & custom synthesis, and environmental assessments.

THERAPEUTIC AREAS: ABC provides development expertise and analytical support for pharmaceuticals and biopharmaceuticals across all therapeutic areas, with particular expertise with inhalation and cytotoxic drug products, as well as those with complex delivery systems.

"It is very rewarding to be recognized as a quality leader by our clients. We serve an industry whose fundamental purpose is improving quality of life, and feel fortunate to be part of that mission. The demand for quality systems, regulatory rigor, and a commitment to continuous improvement is sure to intensify in the years ahead. ABC is committed to meeting that challenge."
— John Bucksath, president & CEO

Acceleration Laboratory Services, Inc. • Lees Summit, MO
www.accelerationkc.com • (816) 525-1150
key locations: Lees Summit, MO
contact: Robert Poe, MBA • rpoe@accelerationkc.com

Drug Life Cycle Stages:
Research & Development – Preclinical, Clinical (Phase 1, Phase 2, and Phase 3)
Drug Substance Production
Formulated Drug Production:
Dosage Form Development, Dosage Form Production, Packaging

Main Service Areas:
Clinical, Preclinical

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

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

KEY INDUSTRY PARTNERS: Polsinelli Shugart PC, Xenometrics, LLC, PRA International, and Xcelience

"Acceleration scored highly in the category of reliability for one pure and simple reason, our associates. The team at Acceleration is highly experienced, many with extensive large pharma experience. As a contract solutions provider, this gives us the unique perspective of fully understanding the challenges our clients face in the drug development process. We work side by side with our client to determine the best path forward. Then we do what we say we will do."
— Brent Taylor, general manager

Agilux Laboratories • Worcester, MA
www.agiluxlabs.com • (508) 753-5000
contact: Steven Guyan • sguyan@agiluxlabs.com

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical, Clinical (Phase 1, Phase 2, and Phase 3)

Main Service Areas:
Bioanalytical, Preclinical

SERVICES & CAPABILITIES: AAALAC accredited, multi-species in-vivo PK services, including CSF rodent collection, cComprehensive suite of ADMET in-vitro assays, discovery bioanalysis, featuring our Discovery 2.0™ methodology, experience in numerous biomarker assays, and GLP bioanalysis

THERAPEUTIC AREAS: Oncology, ophthalmology, CNS, cardiovascular and infectious diseases, and medical devices

"We are thrilled that Agilux has been honored with the CRO Leadership Award in the categories of reliability, innovation, productivity, and regulatory. Following upon last year's recognition, these awards reaffirm our dedication to building long-term relationships with our clients by continuing to provide "Better Data Faster". We are privileged to have the recognition of our industry colleagues, and I am gratified to accept this award on behalf of all the exceptional people at Agilux Laboratories."
— Jim Jersey, Ph.D., co-founder, president & CEO

BASi

BASi • West Lafayette, IN
www.basinc.com • PH: (765) 463-4527
Key locations: Mount Vernon, IN and West Lafayette, IN
Contact: Frances A. Leath • fleath@basinc.com

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical, Clinical (Phase 1, Phase 2, and Phase 3)

Main Service Areas:
Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: BASi offers research services along the entire drug development continuum, including drug discovery (ADME, Neuroscience), bioanalytical (large and small molecule), preclinical toxicology, and pharmaceutical analysis (including *in vitro* bioequivalence).

THERAPEUTIC AREAS: Analgesic, cardiovascular, diabetes, infectious disease, oncology, Neurology, and CNS

KEY INDUSTRY PARTNERS: Pinnacle Technology of Lawrence, KS and Data Sciences International (DSI), the global leader in implantable telemetric physiological monitors

"We are very pleased to be recognized as a leader in our industry for innovation. Our highly skilled employees strive every day to find new ways to solve increasingly difficult problems in drug development. At BASi, we pursue innovation because it is empowering for our clients and our employees. When we pursue innovation, we advance the boundaries of what is possible for everyone."
— Jacqueline M. Lemke, interim president and CEO, VP of finance and CFO

BRI Biopharmaceutical Research Inc.

BRI Biopharmaceutical Research Inc. • Vancouver, BC
www.bripharm.com • (604) 432-9237 x225
Key locations: Vancouver, BC, Canada
Contact: David Kwok or Clara Faan • dkwok@bripharm.com or cfaan@bripharm.com

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical, Clinical (Phase 1, Phase 2, and Phase 3)

Main Service Areas:
Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: GLP Bioanalytical assays (LCMSMS, ELISA, Hybridization, RT-PCR) supported by Thermo-Watson™ LIMS, In vitro drug metabolism assays (P450 / UGT phenotyping, inhibition, induction), In vitro ADME assays (protein binding, mechanistic P450 TDI kinetics, covalent binding, metabolite profile ^{14}C-labeled drugs), In vivo cancer cell line efficacy assays, In vivo (AAALAC accredited) rodent PK, acute tox and tumor xenograft efficacy (subcutaneous and renal-capsule) models

THERAPEUTIC AREAS: Prostate cancer cell biology, antitumor pharmacology, and patient-derived tumor xenografts

KEY INDUSTRY PARTNERS: Oncograph™ Therapeutics Inc. (a patient-derived xenograft cancer biology contract research company), In vitro ADMET™ (a primary human hepatocyte in vitro drug metabolism contract research company)

"For nearly two decades, BRI has become recognized by its pharma and biotech clients for providing fit-for-purpose bioanalytical and DMPK 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

charles river

Charles River • Wilmington, MA
www.criver.com • (781) 222-6000 or (877) CRiver1
key locations: Canada, France, Germany, Ireland, Italy, Japan, U.S., and United Kingdom
askcharlesriver@crl.com

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical, Clinical (Phase 1, Phase 2, and Phase 3)

Main Service Areas:
Bioanalytical, Preclinical

SERVICES & CAPABILITIES: Preclinical services (toxicology and safety pharmacology), research models and services, pathology services, laboratory sciences, agrochemical and animal health product development, and biopharmaceutical testing and manufacturing

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

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

"With the industry at an inflection point with regard to outsourcing, providing high quality scientific expertise, reliable client service, and innovative solutions gives clients the confidence they need to outsource their drug development programs to a CRO like Charles River. We are pleased that our clients recognize Charles River's industry leadership in these areas with this award."
— James Foster, CEO

Chiltern • Slough, UK
www.chiltern.com • 44 1753 512 000
key locations: Asia Pacific, Eastern Europe, Latin America, North America, and Western Europe
contact: Stuart McGuire • stuart.mcguire@chiltern.com

Drug Life Cycle Stages:
Research & Development – Clinical (Phase 1, Phase 2, and Phase 3)

Main Service Areas:
Clinical

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

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

KEY INDUSTRY PARTNERS: endpoint, Medidata, Perceptive Informatics, Oracle, and Avoca Quality Consortium

"Chiltern is delighted to be recognized by members of the biopharmaceutical industry as a CRO leader in quality, reliability, productivity, innovation, and regulatory. Chiltern has been serving clients for more than 30 years and has established a track record around the world as an innovative, efficient, and flexible full service CRO. It is a great pleasure to accept this award on behalf of all Chiltern colleagues."
— Jim Esinhart, CEO

Comprehensive Clinical Development • Miramar, FL
www.comprehensivecd.com • (954) 266-2620
key locations: California, Florida, Georgia, New York, Washington, and Washington, D.C.
contact: Elizabeth Harley • eharley@comprehensivecd.com

Drug Life Cycle Stages:
Research & Development – Clinical (Phase 1, Phase 2, and Phase 3)

Main Service Areas:
Clinical

SERVICES & CAPABILITIES: Clinical pharmacology units with full-service support for early phase studies, clinical research centers with highly-recognized CNS investigators, and a network of leading oncology, neurology and geriatric centers

THERAPEUTIC AREAS: Addiction, cardiology, dermatology, endocrinology, immunology, infectious disease, metabolic disorders, neurology, oncology, psychiatry, and women's health

KEY INDUSTRY PARTNERS: Quintiles

"Comprehensive has grown from a tactical service provider to an integrated development partner, offering a portfolio of services and differentiated capabilities. We are proud of this achievement and our ability to accelerate the research process for our clients. Receiving this honor in the productivity category is a tribute to our employees who deliver professional study conduct services, meeting stringent timelines with the utmost quality."
— Jack McGovern, CEO, comprehensive clinical development

Covance Inc. • Princeton, NJ
www.covance.com • (609) 452-4440
key locations: Brazil, China, Germany, Russia, Singapore, Switzerland, United Kingdom, & U.S.
contact: Nigel Brown • nigel.brown@covance.com

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical, Clinical (Phase 1, Phase 2, and Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

Main Service Areas:
Bioanalytical, Clinical, Preclinical

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

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

KEY INDUSTRY PARTNERS: Covance works with all of the top pharmaceutical companies, as well as scores of small and emerging biopharmaceutical companies. We also have publicly announced strategic alliances or collaborations with Eli Lilly and Company, Sanofi, Merck, Takeda, and Bayer.

"In an environment where every day and every data point counts, it's our relentless commitment to operational and service excellence that earns client trust and confidence. Our talented teams of professionals, with deep drug development expertise, create innovative processes and proprietary analytic tools to deliver what our clients need: high-quality data, consistent project performance, and accelerated timelines."
— Joe Herring, chairman and chief executive officer

eurofins | Lancaster Laboratories

Eurofins Lancaster Laboratories, Inc. • Lancaster, PA
www.LancasterLabsPharm.com • (717) 656-2300 • pha@lancasterlabs.com
key locations: Clogherane, Dungarvan Co. Waterford, Ireland; Lancaster, PA, and Portage, MI
contact: Michael McDowell, VP business development and project management

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical, Clinical (Phase 1, Phase 2, and Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production:
Dosage Form Development, Dosage Form Production, Packaging, Logistics

Main Service Areas:
Clinical, Preclinical

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

THERAPEUTIC AREAS: All

KEY INDUSTRY PARTNERS: We serve more than 800 bio/pharmaceutical companies from virtual to large pharma and biopharma, through a full scope of laboratory expertise.

"If there is one thing that we want Eurofins Lancaster Laboratories to be known for, it is great service. Our strength lies in our ability to combine our outstanding facilities, state-of-the-art equipment, strong quality systems, and highly talented people with a strict focus on delivering a phenomenal experience. We constantly strive to earn our clients' trust and exceed their expectations and we are delighted to receive the CRO Leadership Award this year."
— Dr. Timothy Oostdyk, president

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Harlan Laboratories Inc • Itingen, Switzerland • www.harlan.com • 41 61 975 11 11
key locations: Castellar, Spain; Itingen, Switzerland; Rossdorf, Germany; Santiga, Spain; and Shardlow, UK
contact: Dr. Manuela Leone • crs.eu@harlan.com

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical

Main Service Areas:
Bioanalytical, Preclinical

SERVICES & CAPABILITIES: Harlan Laboratories provides a full range of non-clinical testing to support the pharmaceutical, chemical, agrochemical, biocides, medical device, veterinary, and food industries.

THERAPEUTIC AREAS: All

"These awards are recognition of our commitment to setting the standard for the CRO industry. This was a difficult year for the majority of companies and market sectors, but the businesses which enjoyed the best success were those who remained focused on their core skills to deliver the highest quality and best value products and services to their markets, and who were not afraid to continue to invest in the best talent and facilities to achieve this."
— Manuela Leone, MD., president

IMPACT ANALYTICAL

Impact Analytical • Midland, MI
www.ImpactAnalytical.com • (855) IA.SOLVE [427.6583]
key locations: Midland, MI
contact: Eric Hill • hill@impactanalytical.com

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical, Clinical (Phase 1, Phase 2, and Phase 3)

Main Service Areas:
Bioanalytical

SERVICES & CAPABILITIES: Analytical Testing Services: Actives quantitation, batch release testing, dissolution testing, impurities identification, extractable/leachable analysis, method development/validation/transfer, molecular characterization, problem solving, quality control testing, R&D support, raw material characterization, and stability studies

"Impact Analytical is honored to be recognized by our customers as the leading provider of contract analytical services. Meeting and exceeding customer expectations is our mission, and at the core of everything we do. Our experienced staff works hard to accurately document and deliver the project scope within the customer's budget and timeline on every project. We will continue this excellence in the new state-of-the-art testing facility we are moving into in 1Q 2013."
— Eric Hill, business manager

INC Research • Raleigh, NC
www.increresearch.com • (919) 876-9300
key locations: Argentina, Australia, China, India, United Kingdom, and United States
contact: Neil Ferguson, executive VP, global business development • info@increresearch.com

Drug Life Cycle Stages:
Research & Development – Clinical (Phase 1, Phase 2, and Phase 3)

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, and strategic consulting

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

"INC Research is honored to be recognized as an industry leader in delivering quality services and innovative solutions to our customers. We remain focused on driving operational efficiencies through cutting-edge technologies that help inform strategic drug development decisions - ultimately reducing cost and increasing the value of R&D investments — in support of bringing products to market that improve world health."
— Jamie Macdonald, CEO

inVentiv Health Clinical (formerly PharmNet/i3) • Princeton, NJ • (609) 951-6800
key locations: More than 36 countries including Argentina, Canada, Singapore, Switzerland, United Kingdom, and the U.S. • www.inventivhealthclinical.com
contact: Greg Skalicky, EVP business development • gregory.skalicky@inventivhealth.com

Drug Life Cycle Stages:
Research & Development – Clinical (Phase 1, Phase 2, and Phase 3)

Main Service Areas:
Bioanalytical, Clinical

SERVICES & CAPABILITIES: inVentive Health Clinical provides drug development services, offering therapeutically specialized capabilities for phase I-IV trials, bioanalytical services, and resourcing from a single clinical professional to an entire functional team.

THERAPEUTIC AREAS: Neuroscience, cardiovascular, oncology, and infectious diseases

Jubilant Clinsys Inc. • Bedminster, NJ
key locations: Bangalore, India; Bedminster, NJ; Düsseldorf, Germany; Pradesh, India; and Raleigh, NC • www.clinsys.com • (908) 947-7711
contact: Diana Hinton • dhinton@clinsys.com

Drug Life Cycle Stages:
Research & Development – Clinical (Phase 1, Phase 2, and Phase 3)

Main Service Areas:
Bioanalytical, Clinical

SERVICES & CAPABILITIES: Jubilant Clinsys Inc. is a full-service, global, contract research organization that provides pharmaceutical, biotechnology, and medical device companies with a full range of services in support of phase I – late phase drug and device development.

THERAPEUTIC AREAS: Dermatology, oncology, neurology, respiratory, cardiovascular, ophthalmology, wound healing, central nervous system

KEY INDUSTRY PARTNERS: Large and mid-size pharmaceutical companies, biotechnology industries, medical device companies

"Jubilant Clinsys is thrilled to receive a CRO Leadership Award in the category of productivity. We have invested in hiring the "right" people, those who thrive in an atmosphere of responsibility and excellence. Furthermore, we continuously evaluate our processes to improve our performance and to provide superior value for our clients. This prestigious award validates our ongoing efforts to strive for improvements in every aspect of our client service delivery and our desire to achieve excellence in our work."
— Nayan Nanavati, chief executive officer

MPI RESEARCH

MPI Research • Mattawan, MI
www.mpiresearch.com • (269) 668-3336
key locations: Mattawan, MI
contact: Ed Amat, VP of global sales • ed.amat@mpiresearch.com

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical

Main Service Areas:
Bioanalytical, Preclinical

SERVICES & CAPABILITIES: General toxicology, infusion, DART, safety pharmacology, neurobehavioral sciences, anatomic/clinical pathology, DMPK, *in vitro* services, *in vivo* models, imaging, surgical services/medical device evaluations, preclinical analyses for small molecules/peptides/proteins, clinical bioanalytical analysis, immunochemistry, dose formulation/analysis, environmental/food safety testing, antibiotic potency testing, release/stability testing, and reference standard management

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

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

PAREXEL

Right where you need us®

PAREXEL International • Waltham, MA
www.PAREXEL.com • (781) 487-9900
key locations: Africa, Asia Pacific, China, Europe, Middle East, South America, & U.S.
info@PAREXEL.com

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical, Clinical (Phase 1, Phase 2, and Phase 3)

Main Service Areas:
Clinical

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

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

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.

"Over the past 30 years, PAREXEL has been focused on delivering safe and effective treatments to patients worldwide, through the implementation and refinement of clinical development expertise and leading-edge technology. As one of the first clinical research organizations, we have evolved into a provider of a broad range of services for biopharmaceutical companies of all sizes — including integrated clinical development, regulatory affairs consulting, commercialization services, and technologies that expedite time-to-market."
— Josef von Rickenbach, chairman and CEO

PPD®

PPD • Wilmington, NC • www.ppdi.com • (910) 251-0081
key locations: Austin, TX; Beijing, China; Bells Hill, Scotland; Cambridge, United Kingdom; Madison, WI; Research Triangle Park, NC; Richmond, VA; and Wilmington, NC.
ppdinfo@ppdi.com

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical, Clinical (Phase 1, Phase 2, and Phase 3)

Main Service Areas:
Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: Pre-Clinical and Early Development Services — BioDuro, A PPD® Company, X-Chem; MAB Discovery, Phase I clinic, CMC consulting, pharmacology/toxicology. Clinical Development Services — Full service phase II-IIIb clinical studies, project management, clinical trial monitoring, data management, biostatistics, pharmacovigilance, feasibility studies, therapeutic expertise, biosimilars, adaptive trial design, patient recruitment, regulatory affairs, quality and compliance, IVR/IWR system services, late stage research, registries and observational studies, epidemiology and health outcomes, risk management and REMS, clinical supplies. Laboratory Services — Phase I-IV global central labs, bioanalytical labs, cGMP labs, vaccines and biologics

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

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

"As an industry leader, PPD is committed to excellence, quality, and exceptional service delivery. Innovative technologies, processes, and solutions allow us to work smarter and more efficiently for our valued clients. Strong relationships are built on the successful delivery of projects. Ultimately, however, the greatest contributor to success is our people. It is an honor to be recognized for the efforts PPD employees make to help bring new and improved therapies to patients in need."
— David Simmons, chairman and CEO

Product Safety Labs

Product Safety Labs • Dayton, NJ
www.productsafetylabs.com • (732) 438-5100
contact: Gary Wnorowski • Garywnorowski@productsafetylabs.com

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical

Main Service Areas:
Preclinical

SERVICES & CAPABILITIES: Contract research organization providing GLP toxicology and analytical services.

KEY INDUSTRY PARTNERS: Several years ago, PSL established a strategic partnership with Eurofins' global laboratory network which has significantly enhanced the diversity of services we offer our clients.

"For over 35 years Product Safety Labs (PSL) has been a CRO industry leader, providing toxicology and analytical chemistry services for global regulatory product registration. We are pleased that our clients have recognized our achievements in the areas of regulatory excellence, quality, and reliability. PSL remains committed to offering outstanding quality, competitive prices, and an ever-expanding scope of services."
— Gary Wnorowski, president

Quanticate
A Passion For Excellence

Quanticate • Boston, MA • www.quanticate.com • (617) 973-5119
key locations: Bangalore, India; Bloemfontein, South Africa; Boston, MA; Canterbury, UK; Hitchin, Hertfordshire, UK (HQ); Manchester, UK; Oxford, UK; and Warsaw, Poland
contact: Thomas Underwood • Thomas.underwood@quanticate.com

Drug Life Cycle Stages:
Research & Development – Clinical (Phase 1, Phase 2, and Phase 3)

Main Service Areas:
Bioanalytical, Clinical

SERVICES & CAPABILITIES: Quanticate, one of the world's leading data-focused CROs, specializes in the provision of biostatistics, programming, clinical data management, medical writing, and pharmacovigilance services.

THERAPEUTIC AREAS: Allergy, cardiovascular/metabolic, CNS, dermatology, endocrinology, gastroenterology, hematology, anti-infectivies, infectious diseases, musculoskeletal, rheumatology & osteology, nephrology, renal, & urology, neurosciences, nutrition, obstetrics/gynecology, oncology, ophthalmology, pain management, rare diseases, respiratory and immuno-inflammatory, transplantation, vaccine & virology

KEY INDUSTRY PARTNERS: Clinical Ink and Comprehend Clinical

"Quanticate is honored to be recognized as a top tier organization and industry leader in the area of Innovation. Our company is focused on offering the best possible solutions now and looking at what our customers will need in the future. We believe that the development of technologies such as our innovative study management and data visualizion portal, CliQ is part of the reason that customers have recognized us for this award."
— David Underwood, president and CEO

QUINTILES

Quintiles • Durham, NC
www.Quintiles.com • (866) 267-4479
key locations: United Kingdom and United States

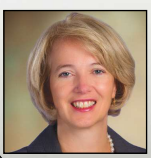
Drug Life Cycle Stages:
Research & Development – Clinical (Phase 1, Phase 2, and Phase 3)

Main Service Areas:
Bioanalytical, Clinical

SERVICES & CAPABILITIES: Quintiles is the world's leading provider of biopharmaceutical services. With more than 27,000 professionals in 80+ countries, we helped develop or commercialize all of the top 50 best selling drugs.

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

KEY INDUSTRY PARTNERS: BioCore for Bioanalytical Services; Samsung biopharma (2011); Nycomed; Takeda-Japan, AZ-Clinical pharmacology



"We are honored to receive a CRO leadership award for innovation, productivity, and regulatory. Our selection is recognition of Quintiles' success in strengthening and transforming our clinical development business to meet and exceed customer needs. We are effective when we anticipate where the market is going so we can guide our customers and remain the clear leader in product development services in the New Health."
— Paula Brown Stafford, president, cinical development

Rho • Chapel Hill, NC
www.rhoworld.com • (919) 408-8000
key locations: Chapel Hill, NC
contact: Kelly Giles • kelly_giles@rhoworld.com

Drug Life Cycle Stages:
Research & Development –Clinical (Phase 1, Phase 2, and Phase 3)

Main Service Areas:
Clinical

SERVICES & CAPABILITIES: Regulatory guidance, protocol development, clinical operations, data management, SAE management, statistical analysis & consulting, project management, CDISC expertise, and IVRS/IWRS

THERAPEUTIC AREAS: CNS, immunology, respiratory, dental, ophthalmology, dermatology, hematology, and infectious diseases

KEY INDUSTRY PARTNERS: Medidata


"Rho is committed to hiring smart people who enjoy thinking both critically and creatively. The innovative people we hire are always improving productivity and our clients notice and appreciate it. We've been providing clinical trials services for more than 28 years now. Over that time we have built a wealth of knowledge and expertise. That experience enables us to deliver high quality regulatory services and guidance to our clients across all phases of drug development."
— Russ Helms, CEO (Laura Helms Reece, CEO, pictured left)

SCYNEXIS • Research Triangle Park, NC
www.scynexis.com • (919) 544-8600
key locations: Research Triangle Park, NC
contact: Clare Murray • clare.murray@scynexis.com

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical
Drug Substance Production:
Primary Process Development, Drug Substance Production

Main Service Areas:
Bioanalytical, Preclinical

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

THERAPEUTIC AREAS: Immunology, antiviral, infectious disease, ophthalmology, dermatology, neglected disease, and antiparastic

"We are pleased to be recognized for our leadership and proven track record of delivering preclinical and clinical candidates to our clients and partners. At SCYNEXIS, we put our expertise and problem solving skills to work for all of our clients so they can confidently move from concept to clinic."
— Dr. Yves Ribeill, president & CEO

Seventh Wave Laboratories • Chesterfield, MO
www.7thwavelabs.com • (636) 519-4885
key locations: Chesterfield, MO and St. Louis, MO
contact: Jody DeBold • jdebold@7thwavelabs.com

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical

Main Service Areas:
Bioanalytical, Preclinical

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

THERAPEUTIC AREAS: Various

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contact: Ralph Lin, Ph.D., global strategy & corporate development officer, president, TR-USA
rlin@snblusa.com

Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical, Clinical (Phase 1, Phase 2, and Phase 3)

Main Service Areas:
Bioanalytical, Clinical, Preclinical

SERVICES & CAPABILITIES: As a global CRO, SNBL provides a full range of integrated non-clinical and clinical services (PhI-IV) with facilities in the U.S., Japan, and Asia. In the U.S., SNBL offers GLP preclinical services, Ph1/2 clinical services, and animal colony management.

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Drug Life Cycle Stages:
Research & Development – Preclinical

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, extractables and leachable, 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), IBD, dermatitis, obesity, and wound healing

KEY INDUSTRY PARTNERS: Biotech, pharmaceutical, and medical device

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Drug Life Cycle Stages:
Research & Development – Discovery, Preclinical

Main Service Areas:
Bioanalytical, Preclinical

SERVICES & CAPABILITIES: Toxicology — general toxicology, developmental and reproductive toxicology, inhalation toxicology, neurotoxicology, genetic toxicology, juvenile toxicology and ecotoxicology; Pharmacology — core battery, radiotelemetry, and RIP/JET; Chemistry — analytical and bioanalytical chemistry, ADME, immunochemistry, and physical chemical characterization; Pathology — immunohistochemistry and stereology; Regulatory — agrochemicals and biocides, program and regulatory services, and environmental risk assessment

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Risk-Based Monitoring: All Talk And No Action?

Laurie Halloran

As the founder, president, and CEO of Halloran Consulting Group, Laurie Halloran has 25+ years of experience in clinical affairs management with pharmaceutical and biotechnology companies and is recognized as an industry expert in improving organizational effectiveness of clinical operations teams.

Almost two years ago, the FDA issued a draft guidance document "letting us off the hook" from what had been standard practice in most registrational clinical trials: source document verification (SDV), the procedure commonly called "100% of 100%," or in layman's terms, a complete verification of every data point for every patient in every clinical trial where data is included to support approval. SDV requires significant resources in terms of time and cost. It tends to be the key activity of CRAs (clinical research associates) or monitors during routine site visits, although there is widespread agreement it should be only part of a monitor's focus to ensure a high-performing site. Reducing the practice to a quantitative risk-based model would free up monitors' time so they may more effectively manage the activities that often cause a research site to veer off track from a regulatory perspective.

The FDA recognizes that SDV requires significant time and resources, and that finding ways to reduce the time required allows the monitor to pay closer attention to other important aspects of a study so that the study stays within regulatory guidelines. While the FDA's guidance sanctions a risk-based approach, and the time and cost savings seem to be potentially significant for sponsors, the adoption of the new practices has been surprisingly slow.

WHY THE SLOW ADOPTION RATE?

What is behind such lukewarm implementation of a much-needed efficiency, particularly one which has been suggested by the FDA? To find out, I have spoken about the guidance's tepid reception with hundreds of sponsor stakeholders from CRAs to CMOs. There is reticence to "be the first," a behavior that I noticed even 20 years ago when I was a monitor. I noticed the risk-averse conduct at the time, but after seeing it still in use decades later, it is apparent that this hesitation to strike out and be first is the reason for slow acceptance of new methods of efficiency. Senior management sees the potential for cost savings in a risk-based model, so many executives issue an edict. But others have their vision clouded; they see only risk, and they want someone other than themselves to act and make definitions all the way down to the level of a procedure. My observations of clouded vision are confirmed every time I present on this topic, and there are questions from the audience that prove that no one wants to take the first plunge off the dock. After witnessing so much hesitation, I see it as imperative we stop quibbling. Get on with it, and take a leap! There is so much to be gained and so much which has proved to reduce efficiency to be lost, that there is no need not to embrace this new mode of operating.

RISK MANAGEMENT PREREQUISITES FOR SUCCESS

Well-adopted risk management practices can be applied to clinical trials with a quantitative and qualitative model established and deployed to enable study management decision making on both protocol and site-by-site levels. What does it take to effectively and accurately implement risk management? The goal is to use a right-sized approach based on the ongoing performance of the individual sites. The role of clinical compliance within sponsor companies is relatively new, and it will ultimately be a critical one to ensure quality control is managed in real time. Additionally, there should be an individual on the study management team who makes an ongoing assessment of the potential risks based on the data being collected through EDC (electronic data collection) and modified with input gathered during the CRA's site management activities, including visits. Another key component to making a risk-based approach successful is to partner with outsourcing providers, and there are two reasons for this: to develop a study-specific monitoring plan and to build a strong feedback

The role of clinical compliance within sponsor companies is relatively new, and it will ultimately be a critical one.

loop so the sponsor is involved in sanctioning changes to the frequency and intensity of monitoring as it occurs.

WHAT TO WATCH OUT FOR

The process can be complicated by several factors, the first of which is to be mindful of how the CRO proposes the budget and scope. Research sites with infrastructure and highly skilled staff are crucial to fully realize the cost savings, but they are often not identified as such when the project budget is initially defined. The gulf between many sponsors and CROs having an open dialogue built on trust may prevent a collaborative approach that is essential to defining the budget because there are many variables that can give the vendors concern about scope issues once the project begins.

I recognize there are companies out there trying a risk-based approach, and I applaud them for their willingness to update their procedures. But there won't be widespread adoption until lessons learned by those who've tried it can be shared publicly to demonstrate how well it works to appease those who are too nervous to take the plunge. Risk-based monitoring is not a panacea and not a one-size-fits-all solution. However, CRAs can and should be teachers, problem solvers, and compliance managers, not data point verifiers and box checkers.

CRO Evaluation By The Small-Company Sponsor

Clinical CRO selection is a critical business process that can be daunting for a small company. A number of high-quality vendors offer services, but selection should be predicated upon a systematic evaluation of distinct areas of competency. Vendors will claim superiority in every area, but all firms have strengths and weaknesses. In most cases you will be assembling a team of expert staff from your own organization, independent consultants, and the selected CRO. For a pivotal trial, in particular, it is crucial that all areas are covered by experienced people.

The following categories are useful for organizing the evaluation:

Protocol Design: CROs that are otherwise capable may be weak in this area. Relying entirely on your principal investigator may also be risky; they may have an academic mindset that is inconsistent with regulatory requirements. Consider using specialized consultants if you do not have the in-house staff. For a pivotal trial, the statistical analysis plan, in particular, should be independently reviewed and validated.

Regulatory Affairs: Examine the regulatory experience and geographic footprint of your CRO candidates relative to your intended geographies. Strong U.S. experience may not be transferable to Europe or Asia.

Medical Monitoring: Do not expect the same level of knowledge as your investigators, but credibility in the disease area and good judgment are critical.

Project Management And Team Stability: A strong project manager dedicated to your trial is needed to ensure tasks and resources are stably aligned. Large CROs with large customers may not give your program the attention or stability it deserves, a trade-off that may negate any advantage it has in depth and breadth.

Site Monitoring: Be sure to evaluate the CRA (clinical research associate) team and their approach to site engagement. These are your primary execution representatives in the field, and they have an enormous impact on patient recruitment and data quality.

Data Management And Specialty Services: Ask for a software demonstration, and perform independent due diligence on any third-party vendors. Understand how end user customer support will be handled.

Legal And Contracting: If your CRO will be managing site contracts, evaluate its legal team and contract templates. Clarity about liabilities and indemnities is essential. If you have a strong in-house legal function, you may choose to contract with sites directly.

Cost: As with most purchases, the lowest price may not be the best choice, while the highest price may not be the greatest value.

With these categories defined, the process is as follows:

- Prepare a detailed RFP and send to 6 to 10 CRO candidates. The clearer you are in the RFP, the better the proposals will be, so spend time on it.
- Review the bids, and look for anomalies or unexpectedly high or low price components, as these often point to a misunderstanding of requirements.
- Contact bidders to clarify as needed, and allow them to update their bids.
- Score the bids in each of the above categories. A simple scoring system of five points per category should suffice.
- Align the scores with your needs, and weight the categories. If you can fill a capability with resources outside the CRO, then that category is weighted less in the overall score.
- Select a short list of top-scoring CROs, and invite them to your offices to give an in-person bid defense. The defense is an all-day event. Put every category on the agenda, and be sure to ask clarifying questions and drive conversation with the CRO's function leads. In parallel you can schedule and conduct your compliance audits at the CRO and partner sites, as the sponsor must verify CRO compliance with all technical, regulatory, and quality requirements, and you should not sign a contract until audits are complete.
- Negotiate contract terms with at least two providers, and defer the final selection decision until you have draft contracts to compare. Don't be shy about asking for concessions or inserting performance incentives. The contracting process will help you narrow down to your final choice.

Clinical trials are inherently risky business activities, but with a methodical CRO evaluation process you can minimize the risks and assemble a capable team for your program.

Peter Covitz, Ph.D.

Peter Covitz has led discovery, clinical, and medical affairs programs in cardiology and oncology. He is presently providing executive consulting services.

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When Outsourcing, Focusing On Low FTE Rates Can Be Costly

At a meeting in December 2012, I spoke with an excited young biologist entrepreneur whose grant application had been funded, formally launching his new company. He had arranged shared lab space and couldn't wait to land an Indian chemistry CRO to get started. I mentioned that there might be a more cost-effective option and offered to discuss this topic in more detail in the new year. His quizzical expression suggested I not wait by the phone.

While outsourcing at all stages of life sciences R&D has become common, it is remarkable that entrepreneurs so often believe outsourcing to a lab more than 10 time zones away is the only option — or even a good option. At a time when access to capital for life sciences start-ups is increasingly scarce, it certainly is possible for a virtual life sciences operation to succeed with a lean, capital-efficient, asset-centric business model, without ever building and staffing a laboratory. But execution of outsourced research requires careful planning and sound management. The siren call of inexpensive FTE rates can be difficult to resist, but for a research-driven business to succeed, leadership has to take a holistic view of operational needs, where contract FTE cost is but one component.

CONSIDER THE COST OF REDOING OUTSOURCED RESEARCH

Project managers typically use variations of the triple constraint system, which can be depicted as a triangle with sides labeled good, fast, and cheap — interdependent properties of a project, any two of which may be optimized, but necessarily at the expense of the third. Life sciences projects cannot escape this reality. It may seem cliché, but sometimes you get what you pay for — if the cost of labor is low, but deliverables fail to meet expectations, finding a new vendor to repeat the work could negate the cost savings and delay important milestones. But more damaging than the incremental cost of repeated work, for companies funded by grants or impatient investors, an extended delay could be terminal.

Selecting a partner for contracted research requires a clear understanding of timeline and quality expectations for projects/products and honest assessment of internal capabilities and aptitudes, both scientific and managerial. Then comes contractor due diligence to assess quality capabilities, reliability, responsiveness, suitability of facilities, access to resources, and compatibility of corporate interests and of culture/personalities. Lacking a good match between sponsor and contractor, failure is a very real possibility. Price should not enter the discussion until compatibility is assured — then, if there is more than one competitor standing, the lower price probably makes the most sense.

SMALL COMPANIES CANNOT ALWAYS MIMIC BIG COMPANIES

When contemplating contract work with distant labs, consider the costs beyond FTE rates. Since the turn of the century, well-funded companies, including contractors, have fueled a huge expansion of R&D centers in countries associated with low costs. However, these companies also have expended enormous resources on frequent travel and complex project logistics, and many have resorted to constructing offshore research facilities, often staffed with expertise imported from the U.S. or Europe. Great, productive working relationships certainly can be, and have been, created across geographic boundaries, and I have had the pleasure of participating in excellent long-distance collaborations over the years. However, successfully building and maintaining truly productive research teams across multiple time zones and cultural boundaries is challenging and, for low-budget operations, often cost-prohibitive.

Recommended CRO selection priorities:

1. compatibility — do they have the skills and capacity, and can we work together?
2. preservation of IP protection and ownership
3. quality/reliability
4. proximity — face-to-face meetings (same time zone preferred, same area code even better)
5. fully loaded cost — FTE rates, extra expenses, shipping, frequent site visits.

The good news for entrepreneurs is that most life sciences hubs have a wealth of high-quality CROs from which to choose.

Roger Frechette

Roger Frechette, cofounder and partner at New England PharmAssociates, LLC, is a life sciences entrepreneur, part-time executive, and consultant with broad pharma/biotech industry experience.

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2 Steps Toward Clinical Outsourcing Success

Tim Krupa

Tim Krupa is president of TSK Clinical Development, a consulting firm providing leadership and solutions in clinical planning, project management, clinical operations, and outsourcing.

Increasing clinical trial costs and lengthening drug development timelines compel the biopharma industry to increase its outsourcing of clinical trials. While such outsourcing is generally successful, often the biopharma sponsor feels the experience could be better. Our challenge is improving the effectiveness of outsourced trials while achieving greater satisfaction for all parties. To improve clinical trial outsourcing, biopharma sponsors should focus on two often overlooked processes: the corporate outsourcing strategy and team building.

BIOPHARMA OUTSOURCING STRATEGY

A biopharma outsourcing strategy clearly delineates the outsourcing expectations to all stakeholders. This strategy begins with a clear understanding of the core competencies to be retained by the biopharma sponsor and the functions to be outsourced. All stakeholders must agree to the expectations of the external partners for both the current and future pipeline. Such agreement is a key to success.

All sponsor stakeholders also must agree to the nature of the outsourcing relationship. Is the intent to simply outsource certain activities? Is the intent to maximize the ROI of the biopharma development dollar? If so, then the biopharma company may only be looking for a "pair of hands," albeit experienced and cost-effective hands.

If, however, the corporate outsourcing strategy seeks a development partner(s) committed to deliver value through experience and expertise, then the outsourcing choice is viewed as a long-term decision. In such partnering, the biopharma sponsor is looking for greater commitment, seeking to engage the CRO's "brain."

And, if the corporate outsourcing strategy seeks a truly engaged development partner(s), the strategy should seek to form a much more interdependent long-term relationship. In this type of relationship, the biopharma sponsor seeks to engage the CRO's "heart."

The successful outsourcing relationship should include a governance structure to oversee all activities. To create a "pair of hands," the immediate line management of the participating companies should suffice. If, however, the biopharma sponsor wishes to create a long-term relationship gaining the "hearts and minds" of its outsourcing partner, a steering committee of executives from each partner is formed and meets at least quarterly to set strategy, resolve issues, and oversee operations.

TREAT TEAM-BUILDING AS IMPERATIVE

All too frequently, outsourcing efforts begin with the contract award. An initial team meeting is called, introductions are made, and the clinical trial begins. This is a big mistake!

Both the sponsor and provider bring experience and expertise to the relationship, and in an effective collaboration, best practices result when the knowledge, skills, and expertise of each team member are used to meet the needs of all stakeholders. Every project should begin with a face-to-face kickoff meeting. No exceptions! The primary purpose of this kickoff meeting is to begin building relationships, learning what each member brings to the team. Funding is always tight; resist every effort to view this as an opportunity for cost savings. This meeting is essential to successful outsourcing. The meeting should last one or two days depending on the complexity of the clinical program and the previous relationships of the participants. Key team members from sponsor and provider(s) should attend. Consider an informal event the evening before as conducive to building relationships. Also, have each team member at the kickoff meeting introduce a member of the other company during team introductions.

The kickoff meeting is generally held at the sponsor's offices, where all team members must make the meeting their sole focus. The phones of all participants should be turned off. In addition, discourage the biopharma team from returning to their desks to attend to business. Instead, use lunch and breaks as relationship-building opportunities. As time allows, incorporate team-building exercises into discussions of scope of work, roles and responsibilities, timelines, and deliverables. Nothing replaces face-to-face encounters when it comes to building personal relationships. Successful outsourcing requires good relationships of fully engaged teams.

If the goal is improving the effectiveness of outsourced clinical trials, a collaborative environment based on trust, mutual respect, and commitment to execution requires, and can best be achieved through, a conscious biopharma sponsor strategy and teamwork. In the words of Michigan's famous football coach Bo Schembechler, "It's the team … The Team …THE TEAM."

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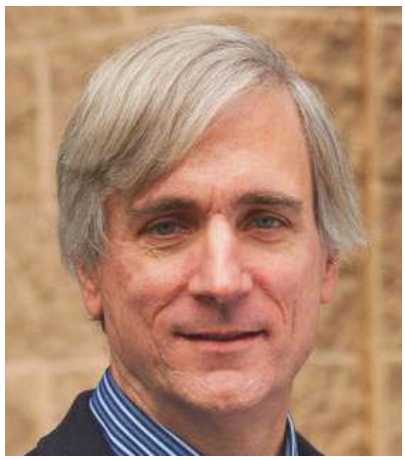

Bruce Rehlaender, Ph.D.

Rehlaender is principal of formulation development at PharmaDirections. He is an expert in bioavailability optimization, formulation of poorly soluble drugs, lyophilized product development, and particle-size analysis.

It's hard to avoid CROs these days. From two-person virtual companies to the largest multinationals, everyone is outsourcing, and like everything else, this trend has its pluses and minuses. For those new to the game, we thought we would address some perceptions and realities we have found in working with pharmaceutical CROs.

PERCEPTION: ONCE YOU SIGN THE DOTTED LINE, THE PROJECT IS IN THE CRO's COURT.

Every CRO brags about its project management abilities and claims it can take your project and run with it. In reality, this is very seldom the case. Without attention from outside, slippage of timelines and scientific misunderstandings tend to be the rule rather than the exception. CRO scientists and project managers are usually doing their best, but they have a lot of other things going on and may not understand your project as well as you thought they did.

PERCEPTION: THE MORE MONEY YOUR PROJECT IS WORTH, THE BETTER SERVICE YOU WILL GET.

Bigger money unquestionably generates more attention from the commission-incentivized BD folks. You may never hear back about a $5,000 project, while a $5 million request for proposal may earn you daily foot massages.

Once the project makes it into the lab, however, you are dealing with salaried scientists who are primarily motivated by two things: desire to do a good job and nagging. Getting speed and quality out of the lab requires excellent oversight, both from the scientific and from the project management perspectives. It also requires strong people skills and an appreciation for the fact that these people are usually overworked and are usually doing their best.

PERCEPTION: QUALITY SYSTEMS ARE A GIVEN.

GMP systems and levels of quality assurance are among the factors that vary most from one CRO to another. Many smaller CROs do not offer GMP services, while some larger ones cannot function except at the highest level of QA review and GMP adherence. At many CROs, the level of quality assurance can be tailored to meet the needs of the customer.

When contracting a CRO, it is critical to clearly delineate the quality level expected. Be prepared not only to pay more for better quality systems but to wait considerably longer for your data. As a sponsor, you have ultimate responsibility for quality, and you must stay involved both to assure the right quality level and to keep your data moving through the quality system.

PERCEPTION: THE MORE A CRO CAN DO, THE BETTER.

The appeal of the one-stop-shop CRO is undeniable. After all, who wants to keep up with multiple contracts and deal with technology transfers? Despite what your sales rep will tell you, the reality is that each CRO has its strengths and each has its weaknesses. The shop that is second to none analytically may be clueless when it comes to addressing your formulation problem.

The big CROs with the widest range of services tend also to be the most cumbersome. We can sometimes get well into a project at a small, agile shop before we even get a quote out of their one-stop competitor. So, although life always looks easier at the Walmarts and Targets of contract research, using smaller, more specialized shops may be well worth the extra effort.

PERCEPTION: THAT REALLY SMART PH.D. I MET AT THE SITE VISIT WILL TAKE CARE OF ME.

All CROs understand the importance of solid credentials in attracting business, which is why you will always meet the best and the brightest when you are still shopping around. Unfortunately, you will not always get the same expert attention once your project is in the door.

Most CROs hire top-of-the-line scientists to fill their upper echelons, but we often see large scientific and experience gaps between that top layer and the scientists who are directly overseeing projects. Even if you get an exceptionally able project leader, they may be saddled with too many other projects and duties to put adequate scientific energy into your challenges.

Making Quality A Priority In Clinical Trials

The words "quality" and "compliance" are ubiquitous in the realm of image-intensive clinical trials. Yet, when it comes to implementing methods to improve and maintain data quality levels, we often concentrate on ways to correct mistakes instead of systems and tools to avoid issues in the first place.

Over the last several years, the industry has developed standardized metrics to measure efficiency, and a subset of those target the speed with which image data is submitted and quality controlled, as well as the speed with which queries are generated and resolved. Core labs typically check 100% of the data submitted, applying significant resources and time checking the completeness of submitted data, and identifying discrepancies between data elements (e.g. images and case report forms), variations from stipulated image acquisition protocols, or the presence of private health information in the data set.

FAST DATA DOESN'T MEAN QUALITY DATA

Investigator sites collate the data they have to send and try to follow the instructions that were given during the initial investigator meetings that took place at the outset of the clinical study. These instructions are complex to begin with. However, when you consider that the person attending the investigator meeting is often not the same person sending the data a few months later, the notion that the sender would assemble the submission following the complex requirements of the study is not always realistic.

Trial coordinators are typically healthcare providers whose primary role is patient care, and the activities required to submit data to an important clinical trial never rise to the level of importance of treating the people under their care. Given the environment, the fact that image-based submissions have discrepancies and generate queries is not surprising. What is surprising is that the best we can do is provide them with systems that allow them to send what they have as fast as possible, so that labs can find the inherent problems quickly and generate and resolve the inevitable resulting queries. This has a side effect: Investigators are bombarded with queries about their data, generating more work on which they can't focus, because they have to take care of their patients. In the best of cases, this vicious cycle leads to delays and cost overruns, and in the worst, it leads to the potential loss of subjects in the study.

SETTING QUALITY STANDARDS AT THE SITE

The issue of data quality in imaging trials must be confronted as close to the point of origin as possible, and that means at the sites. Many imaging trial submissions still rely on paper case report forms and physical media. In some cases, we have been hiding behind a perception that sites don't want to adopt tools to improve data quality prior to submission, and that we should simply acquiesce under the guise of not wanting to inconvenience them. The idea that sites like the status quo is misguided at best. Perhaps what sites don't want are tools they are forced to use but bring no benefit to them, only to those downstream in the process (e.g. simple electronic transfer). It is clear that these dedicated professionals want to do their best, with as few data clarification requests as possible. Error avoidance is better than error correction for all parties, especially the sites.

For that reason, I believe that we have an obligation to provide site coordinators with the necessary tools to avoid errors in data submission assemblies and to check for errors in the image data they are receiving from radiology departments and imaging centers. For maximum effectiveness and impact, these tools should automate the majority of the QC steps on the data being prepared for submission a priori, rather than after it's been received at the imaging core lab. Just as with the advent of EDC (electronic data collection), the up-front approach to data quality assurance for imaging submissions will dramatically increase protocol compliance, reduce discrepancies, and prevent future errors from taking place.

The most successful industries check the complex elements that make up their products, before those elements are sent for final assembly. Quality checks are done in smaller samples and not on 100% of every subassembly that is received. We must adopt this view if we are serious about reducing the cost and delays associated with bringing drugs to market.

Abraham Gutman

Abraham Gutman has had a long career in global technology management. Prior to founding AG Mednet in 2005, he founded and served as president and CEO of Emperative, Inc., a telecommunications software start-up.

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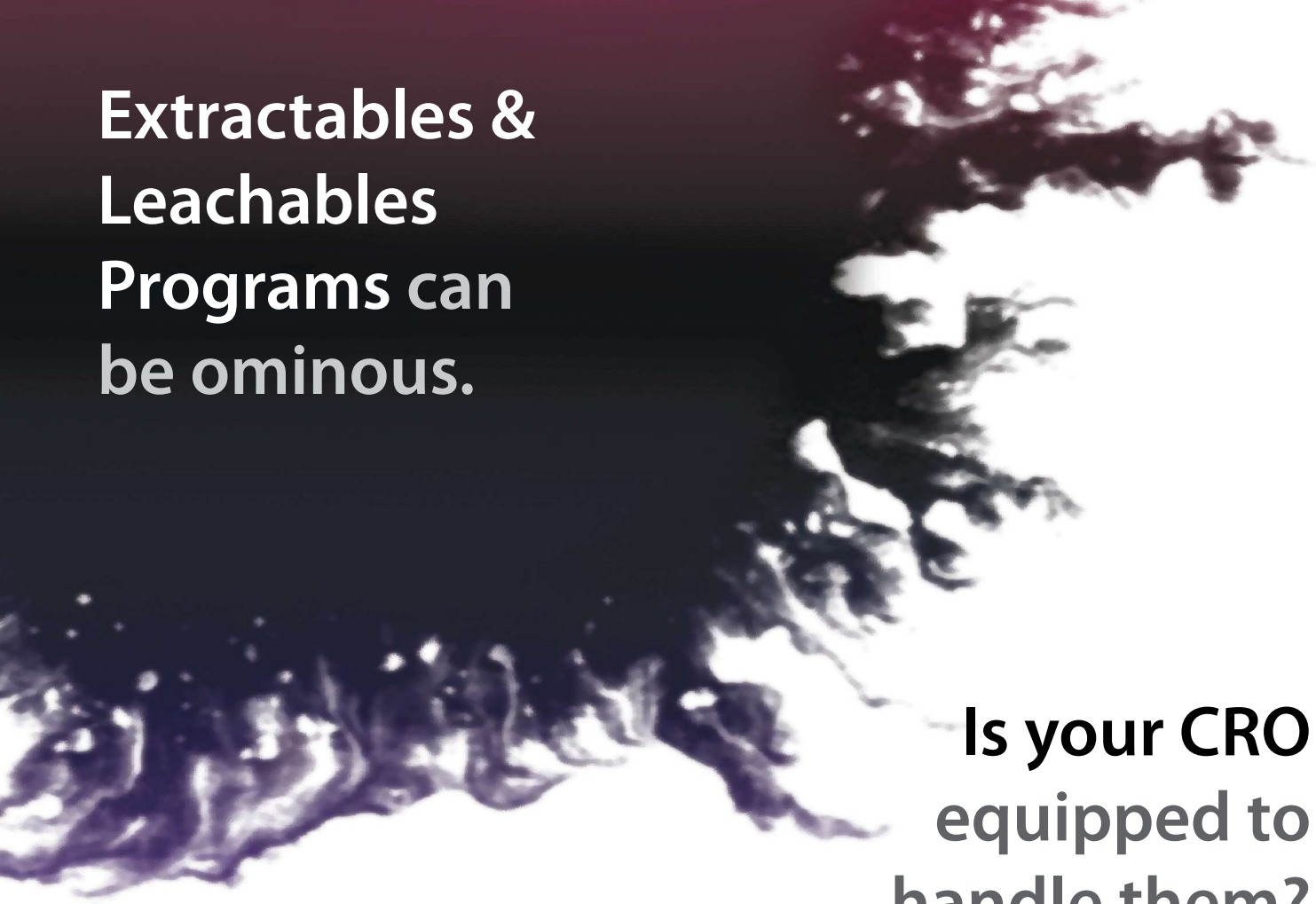

Extractables & Leachables Programs can be ominous.

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Nothing sends a development team into red alert like impurities discovered late in development. Packaging and other container-closure systems can interact with even the most stable formulation. But by applying our principles to your extractables and leachables program, the experts at **ABC Laboratories** will help reduce the risk of surprises and keep your NDA filing on track. Our approach combines a solid understanding of compound chemistry, careful analysis of potential E&L risks, and well-thought-out study design to address regulatory data requirements in an efficient and cost-effective manner.

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