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MAY 2015

THE CHALLENGES OF PERFORMING GLOBAL TRIALS

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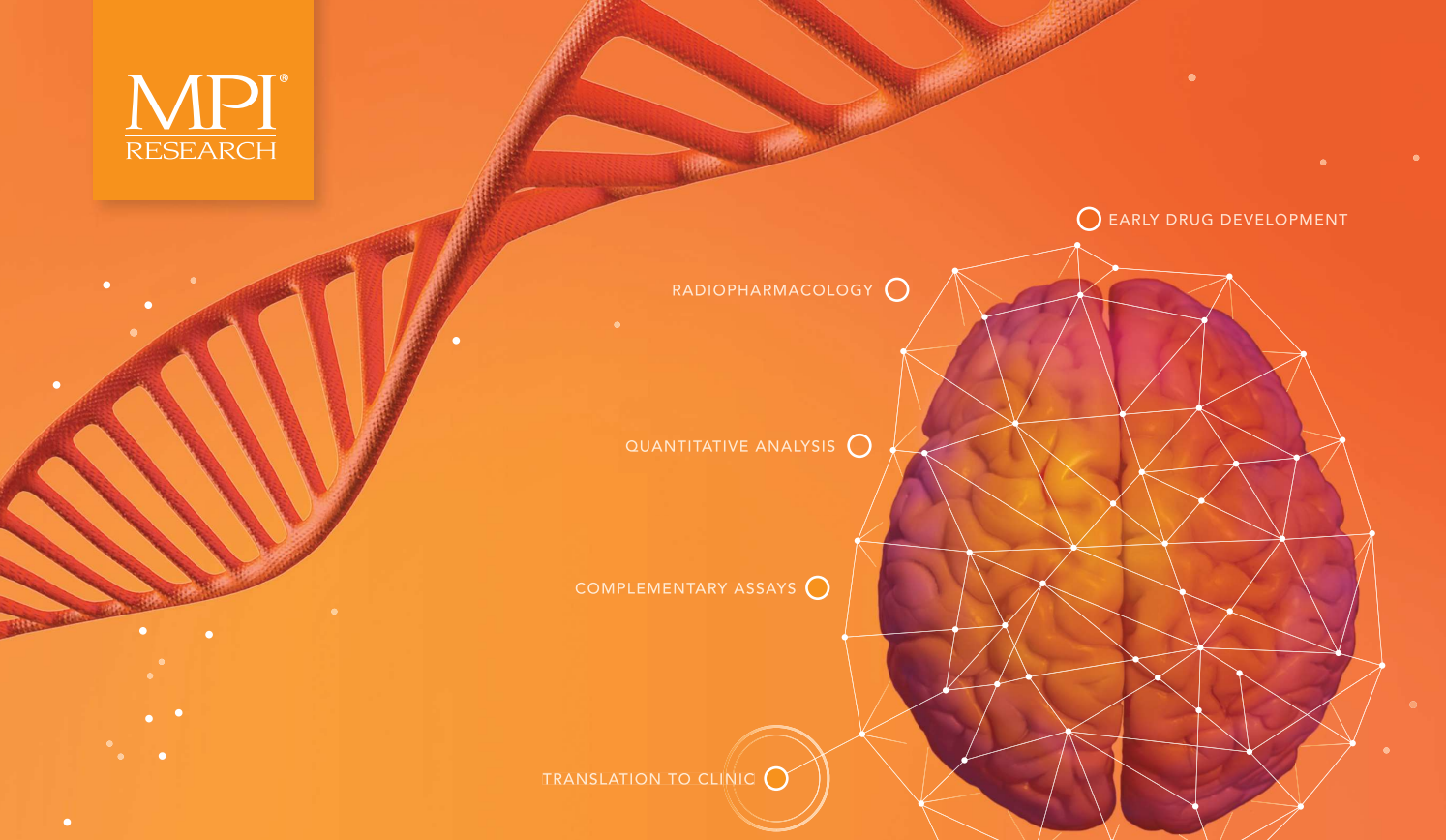

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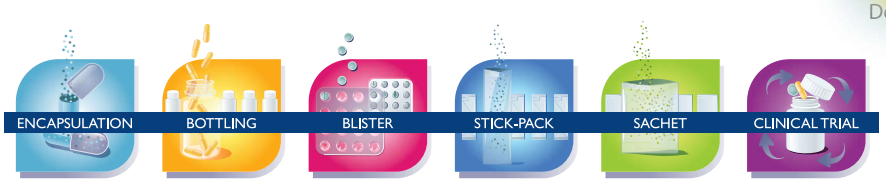

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Quality Is Never An Issue, Until It Becomes An Issue

ED MISETA Executive Editor

I don't spend a lot of time thinking about quality. I doubt that most consumers do, even when purchasing pharmaceutical products. I have leg pain for which I take Ibuprofen almost daily. I also have a prescription medicine I take once a day. Even for these products, which could easily affect my health and well-being, I do not stop to consider the manufacturer, country of origin, or most importantly, whether it was manufactured by a company with a focus on quality. Like most consumers, I just assume it [quality] is there.

HOW DO YOU DEFINE QUALITY

In the world of outsourced clinical trials, you are purchasing a service, not a product. But the result of a trial conducted with poor quality could be even more disastrous: a blown study, an FDA rejection of your data, or worse ... an injured patient.

One of the first books I read on quality was *Zen and the Art of Motorcycle Maintenance* by philosopher and novelist Robert Pirsig. In the words of Pirsig, any philosophic explanation of quality is going to be both false and true precisely because it is a philosophic explanation. "What I mean (and everybody else means) by the word 'quality' cannot be broken down into subjects and predicates," he states. "This is not because quality is so mysterious but because quality is so simple, immediate, and direct."

But is that always the case? If I eat a great meal in a great restaurant and get great service, I will tell my friends and family, "That is a quality establishment." The quality seems simple, immediate, and direct. But are their coolers at the right temperature? Are there rodents under the counters? Are employees washing their hands? I have no way of knowing. Similarly, if a CRO completes your study on time, to your specifications, and meeting all regulatory requirements, they have certainly served your needs well. Unfortunately, there could be quality issues looming that may very well sink your next study. How would you know?

IDENTIFY, MEASURE, AND MONITOR

So how do you identify quality in a CRO? How can you tell if they have a culture of quality or if it matches your own? Is there a way to measure and monitor it on an ongoing basis? These are questions that many clinical executives struggle with daily.

In this edition of our annual CRO Supplement, we take a look at the issue of quality in clinical trials. Mike Howley, associate clinical professor at LeBow College of Business at Drexel University, discusses the research he has performed on measuring quality in trials (page 28). According to Howley, if you're measuring it, you're probably doing it wrong. I hope you will find benefit in this article and the others we have produced for this supplement.

In an industry where medical products are digested by or injected into human trial subjects, quality has to be on the minds of everyone. Or as Pirsig so eloquently put it: "My personal feeling is that this is how any further improvement of the world will be done: by individuals making quality decisions and that's all." L

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MAY 2015 CRO SUPPLEMENT

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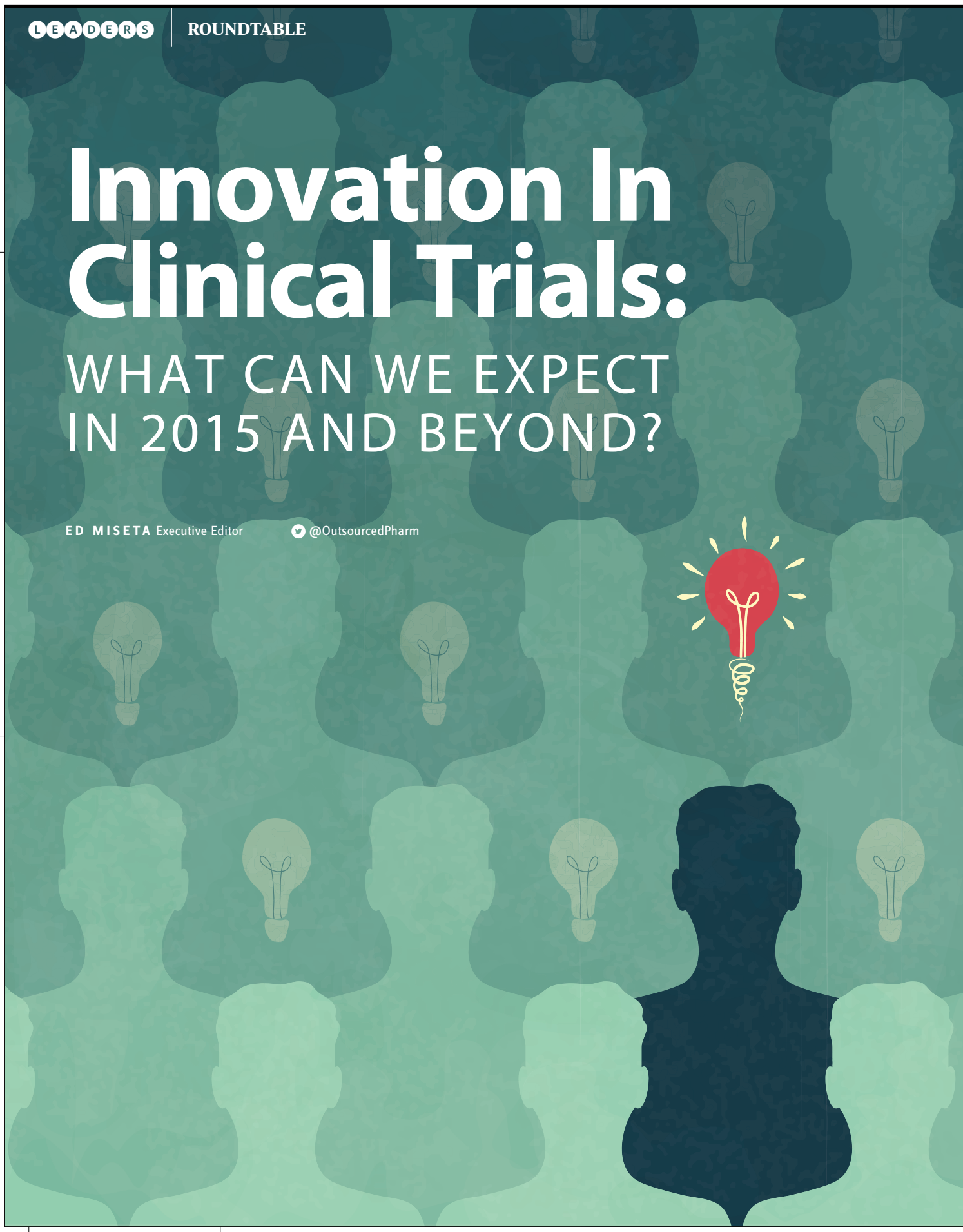
Innovation In Clinical Trials:

WHAT CAN WE EXPECT IN 2015 AND BEYOND?

ED MISETA Executive Editor @OutsourcedPharm



Innovation is a critical topic in the pharmaceutical industry. It is what will help the industry keep on top of quality issues, develop new products, speed needed medicines to patients, and bring down the cost of the entire process. However, identifying where it can best happen and then making the vision a reality is also one of the toughest challenges that sponsors face.

I assembled a panel of some of the best innovative minds in the industry to discuss the trends happening in regard to innovation, and what we can expect to see change in the coming years. The panel included:

CRAIG LIPSET
Head of clinical innovation, Pfizer

JEFF KASHER
President, Patients Can't Wait, LLC

FRANCES GROTE
Senior director, clinical operations vendor oversight, Biogen Idec.

What are a few of the larger trends you are monitoring that could significantly impact clinical trials?

FRANCES GROTE: There are a number of trends that could potentially have a major impact on how we conduct clinical trials within the next few years. A few of these are fairly widely acknowledged, such as using a risk-based approach to monitoring and fully leveraging remote data capture, while others are in earlier stages of evaluation or adoption. Some of the key ones in this latter group are obtaining patient input into clinical trial design, maximizing site relationships with a core group of investigators, and various mechanisms to "virtualize" clinical trial conduct through the use of novel data collection modalities like wearable monitoring devices, apps, and use of EMR data. It's exciting to see our industry becoming more open to real-time innovation, but we still have lots of opportunity to move the needle farther towards innovation.

CRAIG LIPSET: I continue to monitor the proliferation of digital tools (mobile, social, and health information technology), the increasing role of the patient as a participant in healthcare, and the changes in health delivery infrastructure from retail clinics to integrated health networks. Our innovation priorities for clinical trials are anchored around data-driven and structured protocols, making studies easier for investigators, improving clinical trial participant experience, and streamlining the capture of study data.

JEFF KASHER: Those are all good comments. I would add how effectively and consistently RBM is implemented across the industry (both within and outside the U.S.). We also have to consider the economics of clinical research. Early data I have seen indicates that clinical trials reduce an institution's cost per patient and results in improved patient outcomes. Finally, wearable devices and patient-friendly ePRO apps will have a great impact on trials and patient recruitment/retention.

What do you feel will be the larger disruptors in the conduct of clinical trials in the next five years, and will the driving force tend to be sponsors or CROs?

KASHER: This ties in with the previous comments about the role of the patient. I believe the larger disruptions in the conduct of clinical trials in the next five years will be driven by neither sponsors nor CROs...it will be driven by the patients and research sites. Clinical research must become a "treatment option," which means patients will have a large voice in the design/feasibility of trials. Patients, along with their physicians, will match to the trials in which they want to participate. They will discuss the trial, sponsor, and physician on social media and in patient groups, if they are not doing so already.

GROTE: In addition to the novel areas of trial conduct I mentioned above — and no doubt some we haven't even envisioned yet — one of the greatest disruptive forces our

industry has ever seen is the magnitude of and interest in collaboration that's arisen over the past few years. TransCelerate is an inspiring example of how we can create value without sacrificing competitive advantage. Recent inclusion of CROs in that collaboration via the ACRO forum points to how critical collaboration has become for continued success. We are rapidly approaching a time when the economics of developing drugs under our old competitive models will become prohibitive. But in an industry as large and diverse as ours, successful change fundamentally depends on having many parties buy into that change in a specific way that benefits all. That drive for collaboration is also seen in individual sponsor/CRO relationships. With the volume of jobs shifting from sponsors to CROs over the past several years, there's been a broad cross-fertilization of talent. Sponsors are rapidly discovering the benefits of relying on CROs for more strategic and value-add activities than in the past.

LIPSET: In addition to that, I would just add that over the next five years I expect to see radical changes in how clinical trial data is captured (eSource, voice-of-the-patient, proliferation of wearable technologies), as well as where trials are conducted (following the evolving health delivery landscape).

"Wearable devices and patient-friendly ePRO apps will have a great impact on trials and patient recruitment/retention."

JEFF KASHER

What areas are "blind spots" in pharma clinical research (areas that may create big impact but are not currently being addressed or pursued in earnest), and how can sponsors and CROs work together to address them?

LIPSET: That's an interesting question. While we may leverage novel channels in an attempt to reach patients with information about clinical trials, we have a blind spot as to what happens when those patients bring that information to their treating physicians. Data is revealing how many patients wish to learn about research studies, but how few healthcare providers discuss research participation. Anecdotes from patients complement this data, in some instances with stories of physicians actively discouraging participation. Even the most effective message of a trial will be challenged if treating physicians fail to provide encouragement and support. Sponsors and CROs must develop strategies to better engage treating physicians and help to shed light on this important blind spot.

KASHER: We have seen slow uptake on developing multiple sponsor/molecule enduring protocols. Lung Map or iSPY are good examples of this approach. At the end of the day, the molecules which have the best risk to benefit ratio for a specific subpopulation of patients will be the winners. A protocol which can accommodate multiple molecules on an ongoing basis eliminates the repetitive identification and contracting with sites, training is streamlined, and patients can have a better chance of getting an efficacious molecule.

GROTE: Two significant "blind spots" immediately come to mind. One is that our industry continues to lag in maximizing the use of technology. As Craig mentioned earlier, I expect to see that change over the coming years. The other is our fairly universal resistance to acknowledging the realities of enrollment timing. Recent data from the Tufts Center for the Study of Drug Development confirms that across diverse therapeutic areas patient enrollment is consistently much slower than planned. There are a number of potential take-home messages from that, but standard process improvement methodologies clearly indicate that you can't fix a problem if you're not willing to "take it offline" and address it. For many companies the current approach is to continue to plan based on market forces or other goals unrelated to enrollment drivers, and then when problems arise, deal with them in a reactive or crisis management fashion. CRO input is key to gathering up-to-date industry intelligence, both when using technology and improving planning processes. CRO personnel tend to have broader exposure across a number of sponsors. While they can't share confidential information, they do bring a wealth of operational expertise. The biggest challenge to getting the full benefit of that is within the CROs themselves as, from a sponsor perspective, they don't always seem to have robust mechanisms for sharing knowledge within the CRO.

Collaboration between pharma companies and between pharma and CROs can enable innovation. Can you discuss when it is best to innovate together vs. when it is better to go it alone?

GROTE: I'm willing to take the first stab at that one. From my perspective, the question is not WHEN to innovate versus go it alone, but how and what to innovate. Innovation can arise from unexpected sources, and sponsors are not always well-positioned to quickly take advantage of that because they tend to have more rigid SOPs than CROs. Their internal decision-making and approval processes can also be longer and more labor-intensive to

“Our industry continues to lag in maximizing the use of technology.”

FRANCES GROTE

conduct. A robust process for making the most of innovation should allow for rapid evaluation based on clear business cases, empowered decision-making, and prioritization based on the ability to adequately support projects. Historically our industry has operated on the premise that CROs can contribute to operational innovation, but that scientific expertise is the domain of sponsors. Over the last decade we've seen some blurring of those distinctions, especially in the discovery space. But if sponsors and their CRO partners can implement truly effective processes for evaluating and acting on innovation, there's no reason that novel ideas from any source can't be acted on appropriately in a joint fashion.

LIPSET: I think Frances makes some really great points. An old proverb states if you want to go fast, go alone; if you want to go far, go together. The proliferation of collaborations today begins to violate this proverb — initiatives such as TransCelerate are bringing together highly motivated and like-minded peers across companies showing an ability to defy the rule that going together sacrifices speed. Collaboration is the new baseline, but we must continue to differentiate and challenge boundaries. The latter is where we continue to go it alone – the game-changing opportunities that require true leadership.

How can pharma companies better organize to support innovation in their organizations? Can you share a few best practices?

KASHER: In many organizations the innovation group seems to be decoupled from the molecule development teams. This creates a situation where every innovative pilot must be shopped to multiple teams in hopes of finding one who will agree to participate. Implementation of innovation requires an organization where the culture expects/encourages/desires that innovation is piloted and then scaled, if

appropriate, on clinical trials being conducted by the molecule development teams. There is risk of failure, as exists for the molecule itself, but this must be done in a smart manner that protects patient safety and data integrity.

GROTE: Over the past few years our industry has seen a number of different models implemented that are geared to supporting innovation. What most of these seem to have in common is an underlying strategy of allowing a group of people to operate independently of the parent organization. Though different models vary on the level of support, number of personnel, strategic imperatives, and "distance" from the parent organization, it's fascinating to me that all the models appear to have an underlying premise that innovation will happen better outside the sponsor's walls. Potentially that speaks to some opportunities for change within the walls as well. At Biogen we have created a few different approaches to working innovatively — disease-specific innovation units that conduct clinical trials, scientific collaborations to conduct research, and a group focused on a value-based approach to meeting unmet medical needs. While the people working in these areas are empowered to focus on novel opportunities, these units remain an integral and fully integrated part of the larger development organization.

LIPSET: There are many models for large organizations to adopt to support innovation. Some may ring-fence and protect their innovation activities, while others may embed their innovation efforts deep inside their operations. My approach has been the latter — I feel it is too easy to test most anything in a protected sandbox. It is harder to make it work from within the operations, where colleagues will challenge new approaches at every step. But challenge makes the idea more robust and resilient, and ultimately more likely to succeed in the real world in bringing impact to the organization.

Ultimately organizations should not become enamored with ideas. Innovation is about the implementation of appropriate ideas to drive value in the organization. Ideas are often commodities — we all have ideas. The hard work is curating those ideas, implementation, and ultimately scaling what works. But that is how we will return value and make an impact in developing new medicines.

I also look for CRO partners to be aligned and transparent with regard to innovation. Where we can share priorities and goals, we can create opportunities to co-invest that are mutually beneficial. The alternative leaves innovation as just another transaction.

The most recent *Pharmaceutical Outsourcing Monitor* gave a tip of the hat to thought leaders like yourselves. But it also cautioned that we be careful to not overlook the innovative ideas that originate from the worker bees doing their jobs on a daily basis. How can a pharma company's culture help to support innovation, and are there ways to better align the culture of the sponsor and CRO to support innovation?

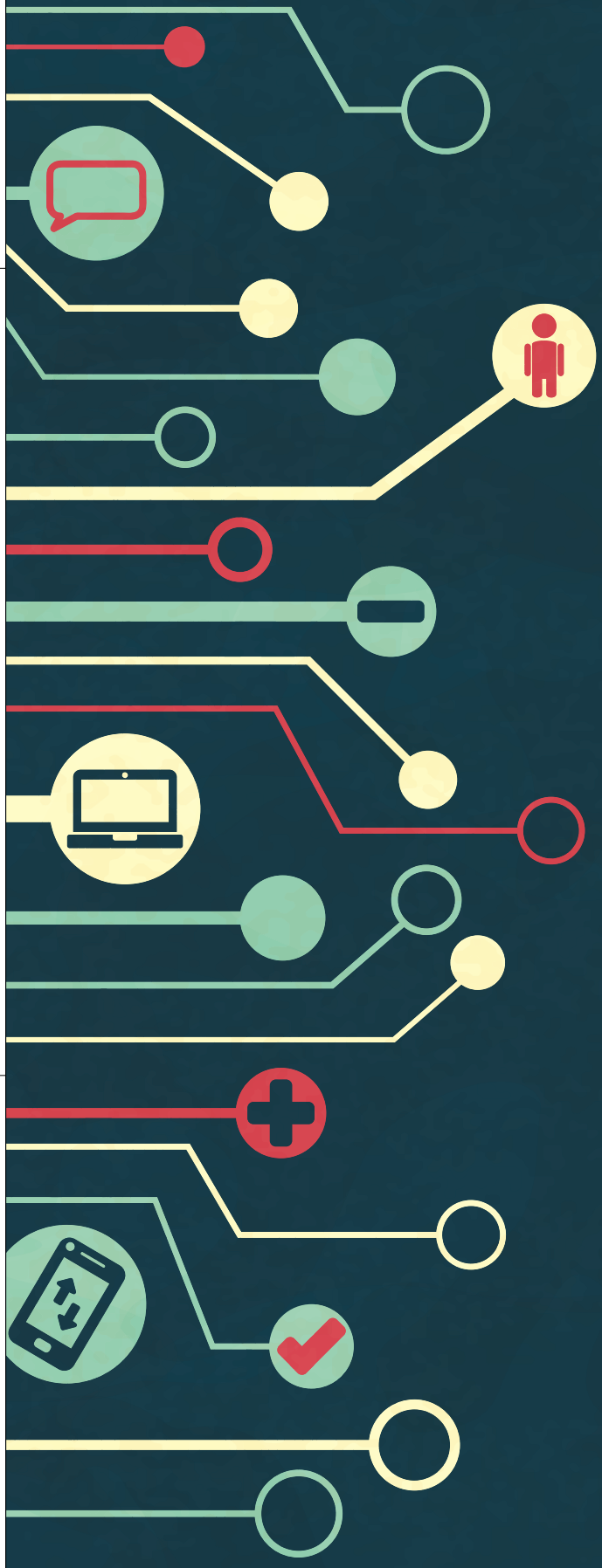
LIPSET: That's interesting. I had actually not seen that. I would say that I am very transparent about the source of good ideas – they don't come from me! I sit inside the operations area at Pfizer and surround myself with the smartest people I can find at all levels both inside and outside the company. My work is to help them bring their ideas to life, with robust business cases and plans to scale where they succeed.

My goal in sharing examples of peers implementing disruptive new innovative approaches is not to champion one idea over another. I share these examples to inspire others and to show them how colleagues are driving to implementation and challenge us all to drive change.

I saw this impact first-hand as we shared our journey with the REMOTE trial. While some of the components worked and others did not, perhaps the greatest legacy of that project is the impact on colleagues inside and outside of my organization in believing that they are not constrained by the way we see our world today. If we all choose to be fast followers, then it's a race to the back seat of the car with no one behind the wheel.

KASHER: Well said, Craig. I completely agree with that. If anyone thinks the innovative ideas originate from the "thought leaders," they are sadly mistaken. The insight, ideas, and sanity checking largely come from people in the "trenches" at pharma, CROs, and research sites. To support innovation, a culture which fosters thinking differently must exist in the face of predominating pressure to go faster and deliver on "quarterly expectations of the street." This is no different in pharma or CROs. Leadership which creates motivation and safety for folks to innovate is desperately needed across the industry.

GROTE: Biogen and our clinical development CRO partner, Quintiles, are jointly focused on how to foster and get the full value of the innovations that arise from the people doing the work. We are collaboratively sponsoring multiple programs to encourage individuals and teams to bring forward innovative ideas and have put a process in place that makes it easy and offers recognition for the "people on the ground" to bring forth suggestions and recommendations. While the formal program supporting this is relatively new, we're already seeing great enthusiasm within both companies and a high level of responsiveness.



TECHNOLOGY AND DATA COLLECTION:

What Has The Potential To Transform Clinical Trials?

ED MISETA Executive Editor @OutsourcedPharm

Two of the biggest challenges sponsors face when it comes to clinical trials are bringing down the cost of studies and patient recruitment/retention. One aspect of trials that truly has the potential to impact both is the latest advances in technology. The Internet, social media, electronic data collection, and mobile technologies can reduce the time, effort, and cost of gathering data and significantly improve the experience for trial participants.

Unfortunately, the pharma industry is not known for its rapid acceptance of new technologies. Even technologies that are proven to work and are given the green light by the FDA can be slow to make their way into sponsor firms. We pulled together four pharma executives with a strong background in data and technology to get their thoughts on where we stand with technology adoption, and what new advancements have the best potential to transform the way we conduct trials. The participants in our roundtable are:

JOE KIM
Senior advisor, clinical innovation at Eli Lilly

ABBE STEEL
Founder and CEO, HealthiVibe

TIM DAVIS
CEO and founder, Exco InTouch

DAVE BORBAS
Senior director, data management at Jazz Pharmaceuticals

What technology-related trend do you feel will have the biggest impact on clinical trials in the coming years?

ABBE STEEL: When Apple recently launched ResearchKit, unleashing the open-source platform and allowing the makers of apps and wearable devices to tap into the capabilities of the iPhone's wide range of inherent sensors, they opened the door for wearable devices to have a greater impact on clinical trials. The ability to gather data passively, only requiring the patient to wear the device, will mean a greater capacity for insight. At the same time, recruitment and retention should be boosted significantly by the convenience and unobtrusive nature of this type of data collection.

The trend toward instant access to real-time data could have a far-reaching impact on clinical trials over the next few years. Studies that incorporate some type of wearable technology that provides a constant data stream may result in faster analysis and data elements we don't currently collect.

JOE KIM: There's no question that patient enrollment in clinical trials is one of the top industry-wide challenges. As Abbe mentioned, technologies that help improve awareness of clinical trials and connectivity between patients and clinical trials are on the rise, and I'm hopeful that they will ultimately enable patients to enroll in clinical trials more efficiently. We're specifically looking at engaging ePatients, or patients who are well-informed and empowered by digital technology and see themselves as equal partners with their doctors and healthcare providers. We are evaluating what ePatients need and want from their digital experience in order to improve clinical research in forums such as clinical trial matching services and online communities/social media. Ultimately, ePatients are on their way to becoming more of the norm rather than the exception, and by mobilizing this community, we can empower ePatients to have a significant impact on enrollment, study participation, design, and more.

DAVE BORBAS: Tablets, data integration between systems, and smartphone technology. Tablets and smartphones are common devices across the world and are extremely familiar to users. That means patients, research center teams, and physicians are comfortable with these technologies and will expect good performance from them. Training that is generalized will be a diminishing need, and training will only be needed on the study applications. These technologies have Wi-Fi and cellular connectivity built in and will enable a wide-area use for research protocols.

On the database back end, integration between systems means that once data is entered it will be available in multiple systems. This decreases the need to reconcile data between them and provides the users common data for basic subject information like demographics, ID numbers, and other types of test results like labs, questionnaires, and ECGs. This means more correct data shared across systems, and it will be more quickly available.

TIM DAVIS: I certainly agree with all of what has already been said. Mobile solutions are ideally placed to address the challenges that today's clinical studies pose and are now being implemented as a means of communicating directly with patients across broad demographics and multiple widespread geographic locations in clinical trials. From enhancing adherence and retention through to the collection of time-stamped and authenticated PRO (Patient Reported Outcomes) data, mobile solutions enable each trial to be designed to include a relevant, standardized, and tailored communication plan. Patients can therefore be prompted to take medication, record data, and attend site visits. Additionally, through the inclusion of timely and relevant educational and motivational messages, they can be better engaged throughout the duration of the study.

What are the most important factors that should be considered when deciding on the use of mobile health technology for a clinical study?

DAVIS: As patient-centricity is now seen as vital to pharmaceutical R&D success, the simplification of methods to capture and report patient data obtained during a clinical trial is critical, helping to facilitate continuous patient engagement for the duration of the study. Therefore, putting the patients and their needs at the center of each solution should be the prime consideration when deciding on the use of mobile technology in clinical studies. Giving particular consideration to the needs of the study population up front can ensure that the technology used to capture and disseminate clinical assessments is both practical and effective in addressing protocol requirements, and is also engaging and convenient for study participants.

BORBAS: The main factor is whether the data is being collected for the primary or secondary endpoints. This will determine how much validation and programming is needed and what type of technologies to use. For example, collecting primary efficacy data that is critical to the success or failure of the analysis of the study means that you need to exercise great care when selecting the technology used and manage the programming and validation very well so that you can withstand the audit questions that will follow. If you are using a visual analog scale that needs to have a precise screen display, then using a Web interface will not provide the control that is needed.

If your data collected has less strict requirements or only uses text displays, then it may be possible to use a variety of consumer-type devices instead of a locked-down or purpose-built device. This is a brief description of the decision area that you have to be concerned about. If you have more critical and strict requirements, your time and cost will increase to match the risk of the project and importance of the data.

"The biggest breakthrough in clinical development will be the increase in patient-centric studies."

ABBE STEEL

STEEL: There are a number of factors that I think need to be considered. At a minimum, I believe any technology should be patient-friendly, applicable to the protocol, a fit for the patient population under consideration, and able to perform remote monitoring. Additionally, it should have the ability to report adverse events to a live person and customized to the country it will be used in.

KIM: Well, there's mobile health and then there's mobile health. If we are talking about new ways to measure a primary endpoint using mobile tech or a wearable device — which in simple, but exciting terms is about moving a traditional endpoint away from an "asking" perspective to one of "measuring" — a body of evidence and credible scientists will need to support this shift. While this could mean more expensive trials, it also could translate into smaller, faster trials. The challenge for a clinical trial team will be to consider how to deploy mobile health technologies for use in clinical trials without any additional challenges than it already takes to manage a study. I do recommend we find a way to practice use of any new technologies before using them in an actual clinical trial, as a way to learn and create best practices.

"We are seeing an increased demand for speed and targeted enrollment of the best patients."

DAVE BORBAS

Patient recruitment and retention has been a challenge in trials for years. What advancements do you see having the biggest impact on patients?

KIM: There are several factors to consider as we strive to advance the development and implementation of clinical studies. In general, we would look to industry to improve raising awareness, increasing Web traffic, using technology, and creating patient-friendly trial designs. In addition, regulations in transparency will be incredibly important to help better educate potential study participants about clinical research. Embracing notions of transparency and turning it into a way to delight our volunteers has the potential to empower individuals to become research advocates. We want to create a community so that those living with a disease and their loved ones not only have a support system, but have information at their fingertips so they can participate in applicable clinical trials. New technology is not necessarily the answer to fix the challenges associated with patient recruitment. Instead, industry needs to work to continue to raise awareness of clinical trial opportunities in addition to telling the story of the value of clinical trial participation in a way that resonates with patients.

STEEL: As technology becomes more sophisticated, and pharmaceutical com-

panies become more engaged with patients and recognize them as key stakeholders in the design process, mobile health technology will impact patients not only during the trial but before the protocol is even designed.

For example, our partnership with StoryVine to create the Patient Experience via a mobile app has led to capturing insights from patients, in their own words, regarding potential study designs and eliciting their feedback regarding potential hurdles to patient-centricity that might prevent them from joining a study or cause them to drop out at a later date.

The Patient Experience provides researchers with a way to see and hear patients who may be halfway around the world, sitting in their own home. At the same time, patients are empowered by this technology. The firsthand input provided by people who are living with disease is having a measurable impact on study design, which ultimately benefits patient recruitment and retention programs.

BORBAS: eRecruiting methods include Web, mobile, and social media. We are moving toward these methods as a primary source of information. Websites are also a good way to interact with patients. We are seeing an increased demand for speed and targeted enrollment of the best patients. These methods will better meet those demands than more traditional methods.

DAVIS: The clinical research industry is increasingly adopting a more patient-centric approach that recognizes that if patients are supported throughout a study, higher levels of compliance and retention can be achieved. Listening to the patient during drug development and partnering throughout their clinical trial experience, as well as the simplification of methods to capture and report patient data obtained during the trial, is now seen as vital to pharmaceutical R&D success. Sponsors and CROs have demonstrated a growing desire to simplify clinical data collection by implementing innovative solutions that provide greater access (in real time) to better quality data, in a more cost-effective way — while in parallel helping to facilitate continuous patient engagement for the duration of the study.

A recent study seemed to show that recruitment via texting may have significant advantages over email. Are there any downsides, and do you expect the use of texting to increase in the future?

BORBAS: I think that despite the impersonal nature of texting, people seem to be comfortable with it, and it is a good way to communicate. You have some limitations with texting

(the size of the message and the content) that are easily surpassed by an HTML email. However, this is still a good way to make an initial connection that can then deepen over time. In addition, technology can support this with text-based reminders when a patient is on a protocol. In both situations, privacy will likely be the greatest concern.

STEEL: As we become more dependent on technology as a society, and more comfortable with the ways in which it permeates our lives, the idea of recruiting via text message becomes more appealing. While texting may provide a greater level of convenience and immediacy, it also has several potential pitfalls. Autocorrect, for example, can completely change the sender's intended message. Errors that are commonplace and socially accepted in casual texting can have disastrous results in the context of clinical trial recruitment where accuracy is imperative.

While most cellphone plans include unlimited free texting, some people still pay for texts, especially outside the U.S., and may not appreciate a recruitment screening model driven through back and forth text messaging. However, given the convenience and widespread use of texting, the trend of using it as a recruitment tool is likely to grow.

"The idea of central or remote monitoring has a huge potential to decrease costs."

JOE KIM

KIM: According to Pew Research Center, among cellphone owners across 32 countries, 76 percent use text messaging via their phones. This is similar to the 83 percent of cell owners in the U.S. who text. Since the invention of the cellphone, the comfort with which we text each other has skyrocketed globally because of bigger screens and how text threads are organized. Data also shows that texting is exploding across all age groups, even those older than 65 years of age. My mother, who is 70, is even using a video instant message app, and she just got her first smartphone this year. The upsides to texting are numerous — the user dictates the cadence, content is short, enduring (enough), and today it's quite normal for threads to go on for days and weeks. Responding to a call to action via text allows potential volunteers to easily weave their engagement into their busy lives. In a previous life, I saw more than one-third of research volunteers responding via a text modality. Contrast that with call centers, where patients are in for an unknown time commitment, or visiting new websites, which have their own learning curves.

Cutting the cost of trials is a concern for most pharma executives. What trends in technology and data collection do you feel will have the biggest impact in this area?

DAVIS: The opportunities mobile solutions hold for the clinical industry are vast, with the potential to reduce the major financial burdens as a result of increasing pressure to progress drugs through clinical trials faster. With trials now commonly being conducted on a global scale, increasing efficiencies in data management is critical, and a "device inclusive" approach (enabling the use of any connected device during studies) can deliver return on investment through a number of avenues. Additionally, the use of a familiar and engaging method of capturing data can reduce missing data points and hence increase quality. This, combined with greater retention of patients, can reduce the need to "pad" the sample size. In large events-driven outcomes trials, by retaining the maximum pool of patients in which to observe events, studies can be brought to an earlier close, reducing their overall cost and duration.

KIM: The idea of central or remote monitoring has a huge potential to decrease costs, given that the lion's share of costs is related to monitoring. In order to do this, the industry needs to explore going digital with its activities, which is of course easier said than done. But, maybe the more challenging thing is to make sure local regulations allow for this approach, for all study-related activities. If you've created conditions for 99 percent of the data to be remotely monitored, that remaining 1 percent will still create the need for a monitoring visit by a human.

STEEL: Most definitely, the biggest breakthrough in clinical development will be the increase in patient-centric studies. These studies are built around the patient, reducing the burden on sites and patients. Today, there are a tremendous number of channels with which to communicate with patients. The Internet has not only facilitated increased patients' access to information, but it has also enabled new pathways for patients to find and access research. As we get the patient voice more involved in the design of trials, I think we will see better data and better retention, which will help to reduce the costs. Incorporate that feedback into bring your own device (BYOD) models, study-specific mobile apps, and disease-specific medical devices (i.e., wireless glucometers), and our industry will certainly see a reduction in overall trial costs.

BORBAS: Based on my experience, data costs are about 20 to 25 percent of a total

> *Listening to the patient during drug development and partnering throughout their clinical trial experience … is now seen as vital to pharmaceutical R&D success.*
>
> **TIM DAVIS**

study. Therefore, reducing cost is more about qualifying patients and reducing the number of screen failures. The other major cost is time. With data management, the question is whether we can decrease the electronic data capture (EDC) build time and database lock time. If so, we can start sooner and faster. However, this is harder to put into practice than it sounds. We have built EDC systems in six-and-a-half weeks, but doing so requires strong support from the entire project team.

Are companies adopting eConsent in trials? What challenges are holding up adoption, and how can they be overcome?

KIM: While I see more and more companies adopting eConsent, challenges still remain. A major challenge revolves around the debate between provisioning devices versus allowing sites to BYOD. While this obviously drives cost, the ghost of EDC past comes to mind as well — many of us still remember the days when stacks of thick, heavy laptops accumulated at the site, each one provisioned for a separate study. At the time, cloud computing had not caught up with EDC, and so this was arguably a necessity. This may not need to be a constraint today. Another challenge is aligning with the local regulations that dictate rules around consenting and monitoring of that consent. The FDA just released its guidance, *Use of Electronic Informed Consent in Clinical Investigations,* and while this should help normalize perspectives on this subject, there are many countries where research takes place and the industry has to be careful to stay within the regulations of every country. eConsent providers can consider redirecting marketing resources in order to generate high-quality legal opinions that help the industry better understand these implications around the world.

DAVIS: Currently there are a limited number of organizations that specialize in the adoption of eConsent processing as a commercial opportunity. At present the results from the first industry pilot studies are only just coming to the attention of the broader audience. Additionally, they are typically focused on the English language versions in the first instance (as any language requirements for multinational studies are adding complexity to the mix) and the focus is still very much on the U.S. market. However, eConsent has been gaining momentum in the last couple of years as organizations are becoming more confident in it and as people are starting to make the case for change in their own companies, and it's set to become more prevalent particularly with the recently released draft guidance on eConsent by FDA.

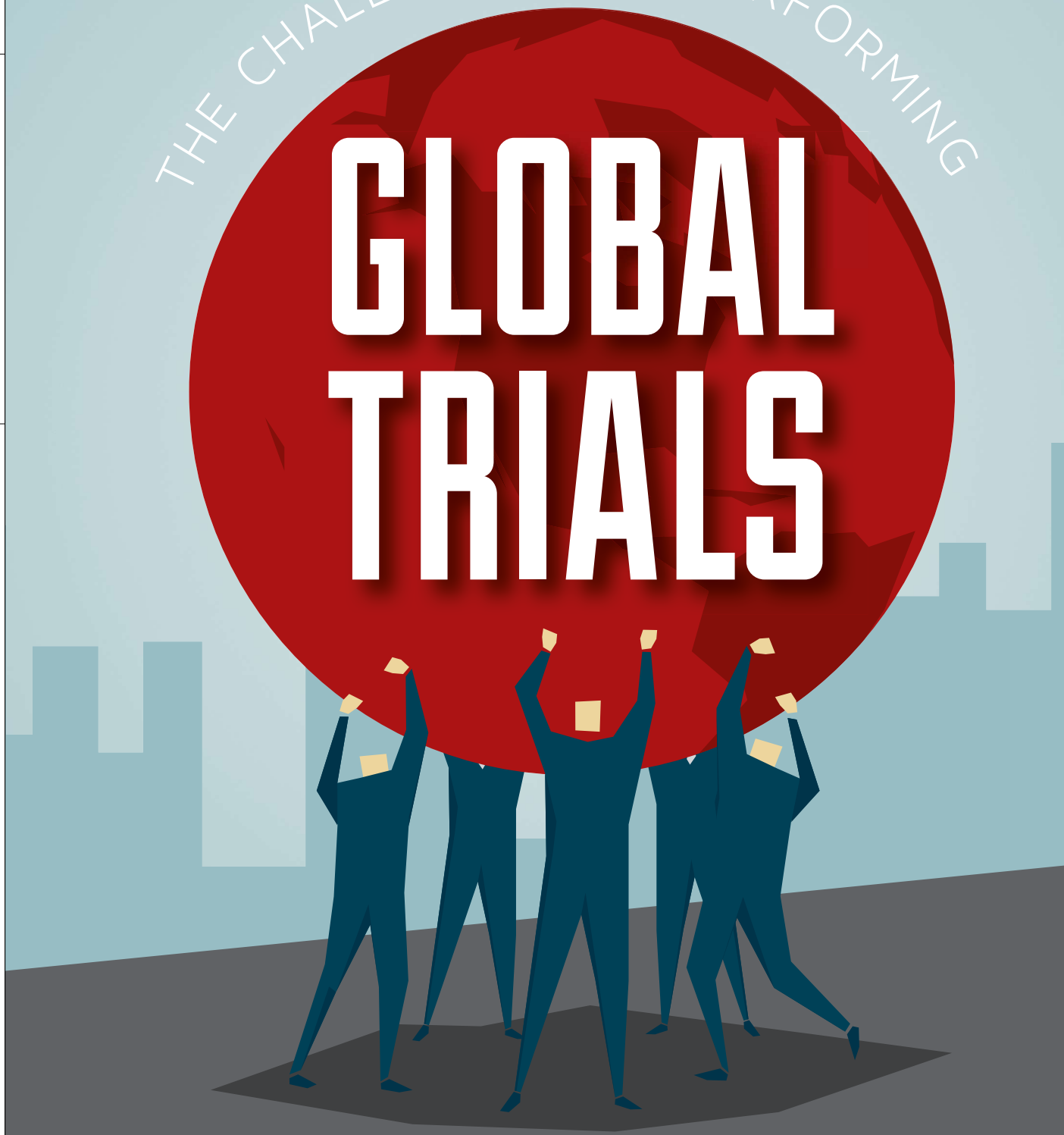
Which mobile technologies do you believe will have the biggest impact on trials?

STEEL: The trend will be toward trial-specific interactive patient engagement tools. An app that reminds patients to take their study medication and about upcoming appointments, gathers data from wearable devices and provides a knowledge base of information regarding the study in a patient-friendly format will impact the overall patient experience, resulting in increased retention and compliance. Patients who are supported throughout the study with meaningful engagement tools will go on to advocate to others about their positive experience, helping to improve not only retention but recruitment as well.

DAVIS: The rise of electronic patient reported outcome (ePRO) tools, especially those implemented through everyday mobile technology, has transformed how CROs and sponsors approach patient engagement in clinical trials. SMS messaging, emails, and in-app notifications now allow sponsors to incorporate a range of reminder, educational, and motivational interventions within study protocols, where previously patients typically would have been left with no support between site visits. Additionally, research sponsors are able to monitor safety, manage compliance (including visit attendance, medication, correct preparation for procedures, home-based actions, etc.), and more closely ensure patient retention throughout the study period. This has not only made clinical trials an easier and more useful experience for patients but has also enabled researchers to collect and process comprehensive data quickly, accurately, and reliably.

KIM: While I will not comment on the specific research or products of other companies, what I can say is that Lilly is committed to transforming clinical development — for science, for innovation, and for those suffering from disease. Part of this transformation includes thinking about new ways to support patients in their successful participation, developing the right medicines for unmet needs, and measuring their efficacy in ways that are meaningful to regulators, healthcare providers, payers, and, most importantly, patients. We are excited to see how aesthetically pleasing, easy-to-use technology can potentially help play a role in enhancing the way research is conducted.

THE CHALLENGES OF PERFORMING GLOBAL TRIALS



ED MISETA Executive Editor @OutsourcedPharm

Clinical trials are never an easy endeavor. Issues with patient recruitment, retention, regulatory, supply chain, and a myriad of other reasons present challenges for both pharma and CROs. When performing global trials, many of those issues are compounded as political turmoil could get added to the mix.

To gain an understanding of the challenges that exist when performing global trials, we enlisted the help of three experts to describe issues they have experienced firsthand.

Our panel consisted of:

JAMES BAINBRIDGE
Associate Director, Clinical Development, Prolong Pharmaceuticals,
discussing Colombia and Panama

LINDA STRAUSE, PHD
Principal and Founder, Strategic Clinical Consultants,
discussing France

ERIN BETTINE, MBA, RPH,
Founder and Clinical Supply Chain Consultant, Erin Bettine Consulting,
discussing Eastern Europe

COLOMBIA AND PANAMA

Be Aware Of Travel Requirements

James Bainbridge has been with Prolong Pharmaceuticals for three years, currently serving as associate director of clinical development. He has worked in the pharmaceutical industry for just under 20 years, working in a clinical capacity for Covance, Ortho McNeil, Ethicon, and Medarex. He also provided legal support to the New Jersey Office of Attorney General and the U.S. District Court in New Jersey before joining Prolong.

How long have you been doing trials in Colombia/Panama?

Prolong Pharmaceuticals is developing products to treat anemias and cancers and has a portfolio of hematology and oncology products in development. The company's lead product, SANGUINATE, is in clinical testing and is focused on treating the comorbidities of sickle cell disease and other disorders caused by ischemia, hypoxia, and/or hemolysis. It is the company's research in this area that led it to trial sites in Colombia and Panama.

The first trial for Prolong Pharmaceuticals in this region was in 2012, so we have been performing trials there for just under three years. Personally, I have had experience performing trials in this region for approximately 10 years. We are able to find patients of sickle cell disease not only in Colombia and Panama but also in other Latin American countries. We certainly have those patients in the U.S. as well, but in looking at patient populations, the regulatory environment, and other considerations, we felt these locations would work well.

Are there specific challenges to performing trials there that are due to the current political climate?

The answer to that is no, and I often find people to be a little surprised when I tell them that. Panama has three branches of government, just like in the U.S., and an elected president. I believe Colombia is currently the fastest growing large economy in South America.

While Panama does not have issues with stability, there is certainly less infrastructure than you might find in more developed countries. Ensuring ethics committees are compliant with ICH-GCP standards can also provide a bit more of a challenge due to the number of ICH-GCP certified ethics committees that exist in Panama.

Editor's Note: Panama was a democracy for most of the 20th century until a coup in 1968 brought the military to power. After the U.S. operation to remove General Noriega from power in 1991, the country became a constitutional representative democracy. The current armed conflict in Colombia started in the 1960s and is a low-intensity war between various groups including the Colombian government, paramilitary groups, crime syndicates, and left-wing guerrillas. However, Colombia has become much more stable of late. President Juan Manuel Santos Calderon, elected in 2010 and reelected in 2014, has made ending the conflict a priority of his presidency.

Getting needed medicines to patients can always be a challenge, but even more so when performing trials in different parts of the world. Were there any supply chain issues you had to deal with?

I find this is not an issue in most major cities, particularly in Colombia. That being said, it may be more of a concern in Panama due to a smaller population. However, using a depot is recommended, when feasible, to avoid import delays. Depots can be used for different reasons, but we had multiple centers so we imported drug in bulk to one location. That way we can provide each site with the minimum supply we believe is required. If a patient comes in, the drug will be available to them. But if no patients enroll or come in, we can minimize the amount of wasted drug. Once you ship a drug to a site, you don't want it back. By having a depot handle the distribution we can

mitigate a lot of that risk.

A thorough audit of the depot, as well as the central laboratory for exporting of samples, should always be conducted. That is just good clinical practice. No one wants to invest a million dollars into a trial only to discover you're dealing with a central lab that is not GCP compliant or puts your data at risk. The same is true of a depot. If the drug in question is a biologic that must be maintained in a required temperature range; not auditing that facility would once again put your trial, or worse your patient, at risk. As the sponsor running the study you have the obligation to make sure the vendor you use is following the right practices.

In Panama, I think the patients seem to be a bit more apprehensive than they are in Colombia, but that may have more to do with the regulatory infrastructure than anything else. In Colombia they have numerous IRBs and a stronger regulatory authority. I believe they do more trials there as well, which builds more patient trust in them.

Patient recruitment and retention is a hot topic in pharma today. Was this a challenge you faced and how were you able to overcome it?

The primary issue, as is the case with many trials, is overstatement of the patient recruitment potential by the investigators and sites. Questions which were very relevant to the enrollment issues were raised only after 50 percent to 75 percent of the enrollment had been achieved. The protocol discussions should focus on foreseeable recruitment obstacles and their impact on enrollment. When those obstacles and concerns are disregarded on the front end, they may carry a heavy cost on the back end.

In addition to recruitment, logistics also became a concern. Patients are often recruited from areas which require travel-reimbursements and even hotel accommodations for spouses and other family members. These payments are reasonable and are generally expected. However, when there is a possibility that travel payments may come into the picture, it is important to have up-front discussions about the areas from which we will be recruiting those patients. In some countries, a city or town just a few hundred kilometers away could end up being a 6- or 7-hour trip. In many cases, the patients must make that journey by bus.

This travel is also highly contingent upon other factors. An advanced oncology patient may not be able to travel great distances. But you may also have patients whose indication is so rare that they are willing to travel great distances to get the help they need. Also a patient won't mind traveling several hours for an inpatient study that might take a week, but would be less willing to do so for a study that requires weekly visits over a period of several months.

Were there any specific regulatory issues you had to deal with that made the conduct of trials particularly challenging in this country?

We do not find the regulatory environment to be an issue, but at the same time communication with the Colombian regulatory authority is constant. The interaction seemed to be very paperwork-intensive, although this was mainly due to the difference in language and necessary translations, not the Colombian government or its regulatory authority. I was constantly getting copies of the paperwork that was going to regulatory authorities, as opposed to a quarterly or for-cause update. INVIMA (the Colombian National Institute for Food and Drug Surveillance) will provide confirmation of receipt, and there are translations and translation certificates.

I do not believe the Panamanian Ministry of Health provides approvals for clinical trials, only the import permit. Panama relies on the EC for the approval.

Editor's Note: While language is generally not an issue, in 2013 INVIMA released a communication stating registration materials pertaining to biocompatibility, risk analysis, sterilization, and clinical studies and test reports could be submitted to reviewers in their language of origin. Summaries of study descriptions, methods, and conclusions must be provided in Spanish.

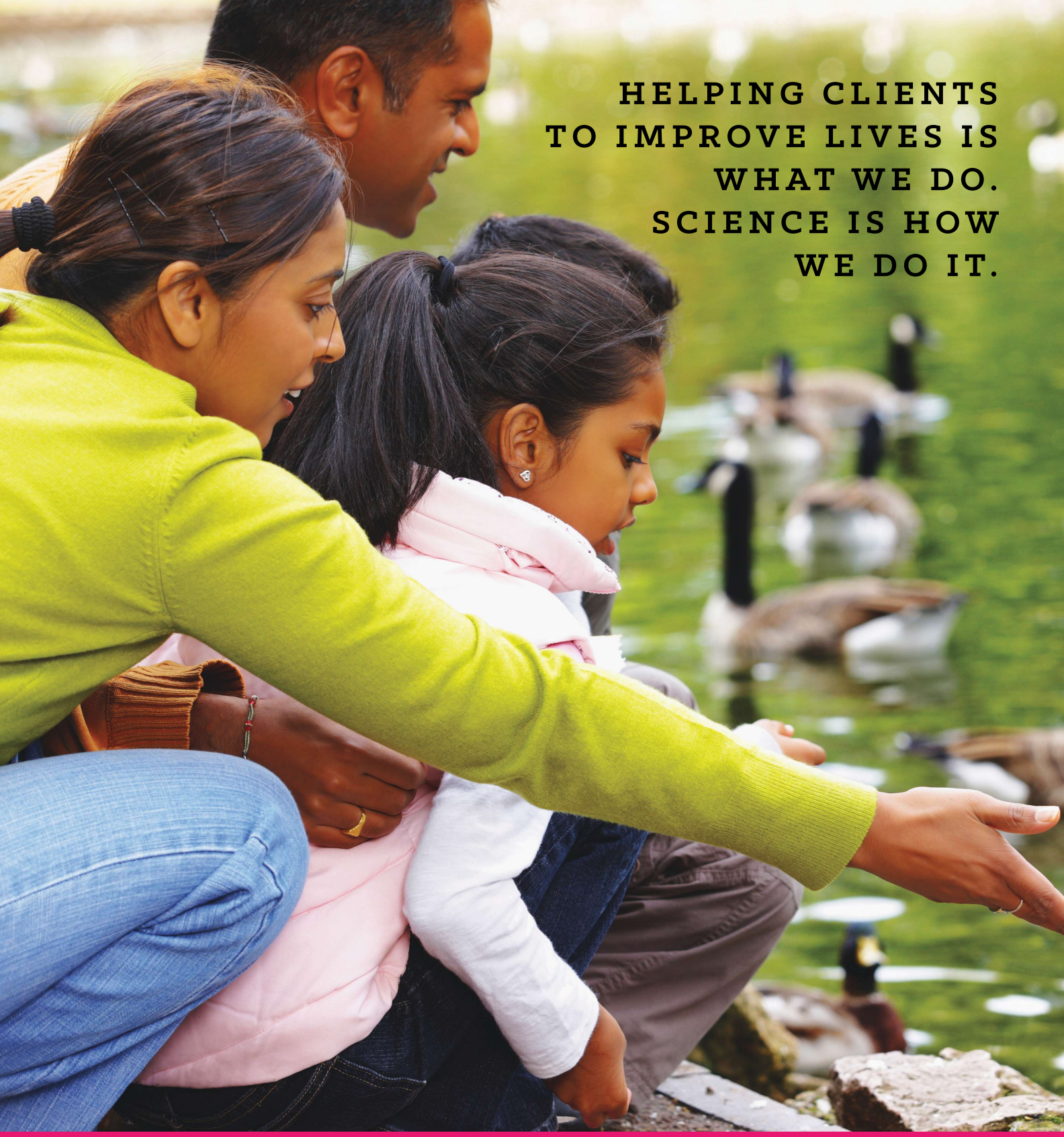
Any thoughts on what the future of clinical trials might look like in this country? Are there any changes on the horizon that might make the conduct of them easier or more difficult?

I believe the future is evident in the growing number of trials that have shifted away from regulatory-burdensome locations such as Brazil and Argentina, and into Colombia due to the increased stability of the government. Panama has seen an increase in clinical trial activity as well. It is worth noting that many of the physicians have trained and/or practiced in United States or Canada. Panama appears to have some site management organizations that actually operate out of Florida. This makes contractual issues a bit easier.

FRANCE

No Direct Patient Recruitment

Linda Strause has a Ph.D. in neurophysiology and biochemistry and has spent over 24 years in education and the pharmaceutical industry working for Quintiles, ACRP (Association of Clinical Research Professionals), Vical, Strategic Clinical Consultants, and her current employer, Strategic Clinical Consultants. Much of her experience is in improving the overall conduct of clinical research programs, with a specialty in oncology and global outsourcing selection and oversight.



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What experience do you have performing trials in France?

I recently conducted three melanoma trials in France. There was a fourth trial I conducted there, but that was pre-EU directives, which really changed the paradigm. France is one of the largest R&D member states in the EU. It has a large population, a good medical system in place, and has great thought leaders and scientists. This makes it a popular place to conduct Phase 2 and Phase 3 trials, and what primarily attracted us there.

Are there specific challenges to performing trials there that are due to the current political climate?

The political situation is stable and there were no concerns that we had in regard to the political climate.

Getting needed medicines to patients can always be a challenge, but even more so when performing trials in different parts of the world. Were there any supply chain issues you had to deal with?

There is a QP (qualified person) release that is required to ship investigational products into the EU. Most U.S. companies get QP release out of the U.K. and once you have a qualified person release your product, it can be distributed throughout the EU. However, when shipping to France, there is an additional release that is also required to be completed.

Another way that France is different from the U.S. is in regard to privacy requirements. For example, you cannot use both initials and birthdate, which is how most case report forms are completed. We needed the birthdate because most protocols call for patients to be over the age of 18, and that is how we would determine age. To deal with this issue we actually came up with a code to use throughout the EU.

Patient recruitment and retention is a hot topic in pharma today. Was this a challenge you faced and how were you able to overcome it?

In France, patient recruitment can be a little tricky because they do not allow for direct patient recruitment through billboards, the Internet, or other forms of advertising. All recruitment must be done through doctors and patient organizations. Patient consent forms are also much simpler than they are here in the U.S. There is an information sheet that cannot be longer than two pages. So often what we did was have a complete informed consent and a separate two-page information sheet to comply with that requirement. Everything is written in French so there are a lot of translations that have to be performed as well.

Because our study was for melanoma, we worked primarily through the physicians, because that made the most sense to us. They did the outreach and connected with hospitals as well. I have found you are really at the mercy of the investigator. The investigator drives everything, and I think that is true throughout the EU.

Were there any specific regulatory issues you had to deal with that made the conduct of trials particularly challenging in this country?

Ironically, the healthcare in Europe is different than the healthcare here. For example, you have to publically disclose your clinical trial for 90 days before you can do anything. That can be a challenge because there is certain information you need to disclose, but because it is public you don't want to disclose any proprietary information that should be kept confidential. I have never heard of anything coming from this requirement, but if someone felt the trial might be unsafe for some reason, they would have the opportunity to make their voice heard.

The EU directive was meant to harmonize across all member states but also allowed each member state to incorporate it into national laws. France was rather slow in implementing the directive. I do not believe that happened until several years after the directive was issued. For that reason not all EU states are created equal, and sponsors will have to do some research into the specific EU nation they wish to conduct trials in.

But at the same time, France does have a true central ethics committee. It is one committee that governs all of the hospitals in the country, which makes working with that committee much easier.

Any thoughts on what the future of clinical trials might look like in this country?

I don't think so. It is one of the largest countries in which to conduct trials and I don't see that changing. The investigators and key opinion leaders who run their labs, and the physicians who work for them, are really amazing. They also do a lot of speaking at conferences.

Biologics are big right now, as are bio safety committees. France has a very active one. As we transition into personalized medicine, I believe this will be a key place for pharma to conduct trials for years to come.

EASTERN EUROPE

Complex Supply Distribution

Erin Bettine is a clinical supply chain consultant with over 20 years of experience in pharmaceutical and biotechnology product development. Much of her career was spent as Head of Clinical Supply Management at Wyeth Pharmaceuticals. In 2008, Erin joined the International Partnership for Microbicides (IPM) managing HIV prevention product development projects. More recently, she led the Clinical Supply Chain group at Nuron Biotech.

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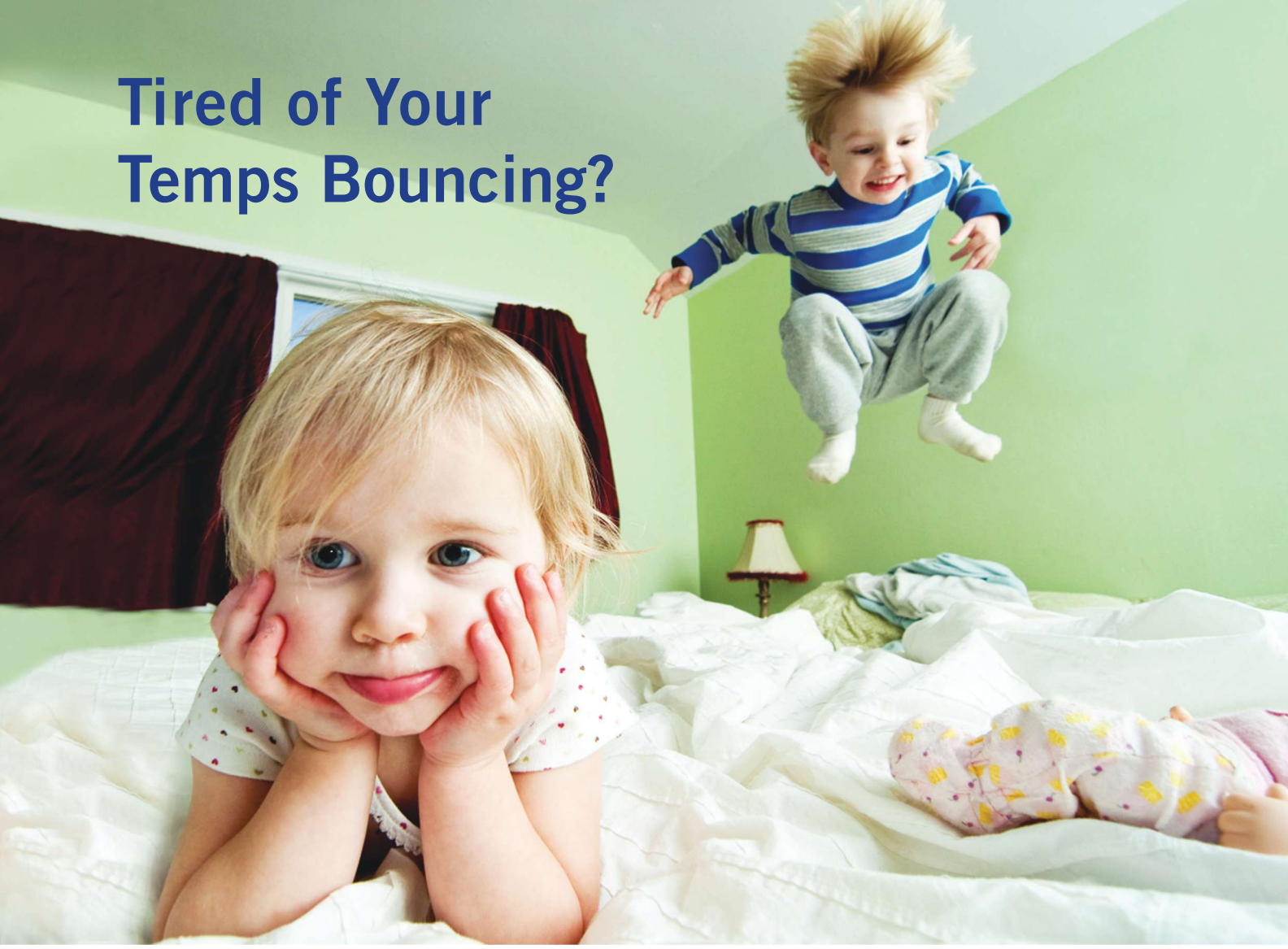

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How many years' experience do you have performing trials in Eastern Europe (including Belarus, Bulgaria, Croatia, Hungary, Poland, Russia, Serbia, Ukraine)?

I performed trials in this region for two years, from mid-2012 to mid-2014.

Are there specific challenges to performing trials there that are due to the current political climate?

Fortunately, the political climate in Eastern Europe did not have a noticeable impact on the trials that I was involved with. Minor protests and uprisings did not prevent site and CRO staff from performing their duties. Even during the first few months of the Crimean Crisis, patient visits, monitoring visits, and supply shipments continued as scheduled. Our trials completed shortly thereafter. There is no doubt that the potential for political instability carries some risk, and that must be weighed against the potential benefits. In our case, this region was able to recruit patients very quickly. I have heard of other clinical trials in which some Ukrainian sites had to be closed due to the conflict. This risk was mitigated by the involvement of other, less volatile, regions.

Getting needed medicines to patients can always be a challenge, but even more so when performing trials in different parts of the world. Were there any supply chain issues you had to deal with?

Supply distribution is complex in many regions, maybe a little more so in Eastern Europe. It was helpful that our clinical supply production site and central warehouse was in a European Union (EU) country. This made the movement of material to sites in the Eastern EU countries, i.e., Bulgaria, Croatia, Hungary, and Poland, fairly easy. It was more challenging in non-EU countries of Russia, Ukraine, Belarus, and Serbia, with requirements for import licenses and permits. Each of these countries has different requirements and timelines for approving the importation of clinical supplies.

After approval, the time needed to schedule and transport the supplies, as well as the courier cost, can also be significant. It was, therefore, essential that depot warehouses be established in those non-EU countries so that supplies were in country well before supplies needed to be shipped to the study sites. Employing a CRO with local regulatory expertise and a CMO with local logistics expertise was critical to our successful supply distribution.

Patient recruitment and retention is a hot topic in pharma today. Was this a challenge you faced and how were you able to overcome it?

Currently, there is less competition from sponsor companies for investigators and patients in these emerging markets, compared to the more traditional clinical trial locations. This, combined with the large pool of treatment-naive patients, good access to healthcare infrastructure, and highly motivated investigators, made the patient recruitment process quite rapid. In fact, the rate of patient recruitment sometimes threatened to exceed the available drug supply, and investigators had to delay enrolling new patients into the study. This was an unexpected situation, quite opposite of my usual experience in which recruitment lags behind projection. So, the challenges were to accelerate the delivery of drug supplies and to maintain a good relationship with the investigators during the delay.

Patient retention and compliance was also quite good in this region. This may have been due to the indication being studied and limited access to alternative treatments. Even though many patients had to travel a great distance for scheduled visits, very low dropout rates were observed. It was important to have an adequate visit window and to dispense enough extra study medication to continue treatment when visits were delayed due to weather and other travel obstacles.

Were there any specific regulatory issues you had to deal with that made the conduct of trials particularly challenging in this region?

The regulatory requirements for the Eastern European countries that are part of the EU are well-established and easier to navigate, although the timelines for approval of the Clinical Trial Application (CTA) can vary between member states. In some of the other countries, specifically Russia, Ukraine, and Belarus, there have been recent changes in regulatory guidelines and processes. Reorganization of the Ministry of Health in Russia and changes to the ethics approval process in Ukraine initially produced some unexpected delays. But now things have adjusted, and the process is improved compared to the time before the changes were implemented. Overall, there has been an effort to decrease the difficulty of getting trials launched in this part of the world while at the same time ensuring the protection of human subjects and setting standards for investigational site qualification.

Any thoughts on what the future of clinical trials might look like in this region?

I expect the clinical trial activity in Eastern Europe will continue to increase. These countries are interested in the revenue and access to new medicines that clinical trials bring. Recent changes to the regulatory processes have made it more feasible, and often quicker, to initiate trials in this region. As sponsor companies gain experience in these countries, realizing the benefits of a large, diverse population and becoming comfortable with the quality of investigational sites and clinical data, it is likely that more global trials will include this region.

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Why Are More Patients Not Sitting At Your Decision Table?

ED MISETA Executive Editor @OutsourcedPharm

Although patients are learning more about clinical research and getting more involved in clinical trials, they oftentimes are still not invited to meetings at the trial design level. This occurs, despite the fact that both sponsors and patients have valuable information that could be shared with each other.

"The whole topic of patient centricity is really about bringing people together," says Paul Wicks, VP of Innovation for patient network PatientsLikeMe. "Although engaging patients early on in the design process is still in the early stages, listening to patients as if they were partners is going to be a significant paradigm shift for the industry."

The trial design process involves answering a lot of questions, such as what should go into a trial, what should be measured, what logistical difficulties will be faced, and how many patients should be recruited. There are a lot of decision-makers involved in answering those questions, including executives, scientists, clinicians, and representatives from legal. Ironically, the only stakeholders who generally seem to be missing from that table are the people who are going to benefit from the medication, who will decide whether or not to take part in the study, and will then decide whether or not to stick with it.

Why has pharma not gotten patients more involved in the trial design process? And why is the adoption of this paradigm not moving ahead at a faster pace? Wicks believes there are three primary reasons.

WHY CHANGE WHAT YOU'RE DOING?

"I believe the first reason is inertia," says Wicks. "When something has always been done a certain way, it is very easy for people to keep doing it the same way. I think there is also a belief that some of those internal stakeholders speak on behalf of the patients, particularly the physicians. But while physicians are clearly experts in the disease and the treatments, they are not experts in having to live with the disease. A clinician may have views on whether or not a pathway, molecule, or side-effect might be disruptive, but they are not going to have insight into how a woman with a job and a child in school will be able to fit weekly clinical visits for an MRI scan into her schedule."

Asking executives, regulators, or scientists to try and understand a trial from the patient perspective might be an impossible task. However, with the digital technologies currently available, it is easier to get patients to answer those questions themselves. "Imagine a cell phone company trying to design a new device for young people and doing so without talking to the users," notes Wicks. "Or perhaps they just talk to the parents of the users. Parents might be able to discuss all of the features they would like to see on the device, but their opinion would be a poor proxy for the ultimate user. While that model is a nonstarter in the consumer world, in clinical trials it is simply how we have always done things."

LEGAL, SAFETY, AND REGULATORY ISSUES

Another reason sponsors might not interact with patients relates to legal, safety, and regulatory issues. These are definitely real issues, according to Wicks. If a patient showed up and started talking about the side effects of a drug, that information would have to be reported to the drug safety department and reports would have to be filed in a timely manner. There are also issues around companies potentially paying patients to take part in surveys or sitting on advisory committees. Sponsors have to be careful not to cross any lines, particularly if the drug is not yet on the market.

Wicks notes there are also issues

around patient confidentiality. If a sponsor speaks to 200 patients about a trial they are designing, there is a possibility that confidential information shared by patients might leak out somewhere. That possibility has to be properly managed from a risk point of view.

"There are some real concerns here," says Wicks, "but fear of those issues might also be used by some companies as an excuse to not talk to patients. This is a real challenge to some companies that want to better engage with patients but have legal and regulatory personnel that are always quick to say no. From their viewpoint, engaging with patients is simply not worth the risk."

Wicks disagrees with that point of view. He notes sponsors need to take a closer look at the legal, regulatory, and safety risks that exist from not engaging with patients. There is certainly risk of launching a product no one wants. There is also risk in designing a trial that no one signs up for, or giving trial patients a drug that they refuse to take. To navigate this dilemma, he states each company will have to develop its own playbook to ensure all employees are taking the appropriate precautions. Every company will likely have a unique approach, as one size will not fit all.

WHAT IS THE APPROPRIATE METHODOLOGY?

Once companies get past the internal inertia and legal/regulatory blockades, they will need to develop an appropriate methodology for interacting with patients. This can also be a challenge for many sponsors. If you are preparing to move into a Phase 2 trial and want more patient involvement, what exactly do you need to do?

There are a multitude of ways to elicit feedback from patients, including market research surveys, ad boards, social media listings, and more. But Wicks notes there is a playbook to be followed for each of those options. You would need to know who to commission them from, how much they cost, how effective they have been in the past, and more. Even when you decide on the best option to reach your targeted patient population, you will have to decide whether to speak to one or 50 or 500. Other questions you will need to answer are:

- How many times should you meet with them?
- How much information should you share?
- Should you have them sign a contract?
- Should you pay them and, if so, how much?
- Should you hire someone to be your advisor?

These are all unknowns that have to be considered before engaging. When considering these questions for the first time, they can be confusing and complicated, especially when undertaking them in a large organization. Without the support of management, this project will be an uphill struggle.

CHOOSE THE RIGHT ADVOCATE

Once you overcome these resistance challenges and formulate a plan of action, finding the right person to head up your patient advocacy efforts is not going to be easy. The people who seem to have the best skills at interacting with patient advocacy groups typically lie on the commercial or marketing side of the house. They tend to be nonscientific, do not get involved with research, and are generally not invited to trial design meetings. The M.D.s and Ph.D.s who do get invited to those meetings are used to reading scientific journals and performing scientific tasks. Drop in someone from patient advocacy who has spent most of their time providing grants to nonprofits and charities, and you often end up with three sides that do not even seem to be speaking the same language.

"The challenge for sponsors is figuring out how to reconcile these disparate world views," says Wicks. "We are basically trying to create a patient-engagement science, three words that do not generally go together. We need to take the opinion of one patient and turn it into a replicable method that can be run by another sponsor, CRO, or university with similar results each time. For many sponsors, that is a brave new world."

A PLAN FOR SUCCESS

To get patients more involved in the design of clinical trials, there will clearly be many challenges to overcome. In the long term, Wicks would like to see two things occur to make the vision more of a reality. The first is patient-centric decision making being made earlier on in the drug-development process. "This should not just occur at the clinical trial level," he says. "Patients need to be brought onboard even at the point of deciding what molecules to select from the portfolio and push forward into human trials. Patients should have a voice in deciding where the real unmet needs are."

Second, he would like patient participation to move up what is called Arnstein's Ladder of Citizen Participation. The ladder shows who has the power to make important decisions. It goes from nonparticipation at the lowest level, to tokenism, and then citizen control at the highest level. Wicks would like to see more instances of patients being consulted and actually given responsibilities during the course of a trial. As an example, he cites a recent trial for breast cancer where 40 or 50 participants were added to the advisory board for the trial and given responsibility for making translations of the recruitment material.

"From the patient perspective, there is a huge difference between someone from a drug company asking you for help versus the company recruiting and training you and giving you some amount of responsibility for the success of the study," says Wicks. "As an industry, we need to move from consulting people to actually working with them as partners. At the extreme end of this it could involve drug companies actually employing patients in advisory capacities. I believe this will be necessary to overcome the three barriers. There will no longer be that negative inertia because this effort will be done internally. We will have created a playbook that takes us through the minefield, which will give all stakeholders more confidence in the methods." L

Measuring Quality In Clinical Trials: Why You're Probably Doing It Wrong

ED MISETA Executive Editor @OutsourcedPharm

Quality is undoubtedly one of the top concerns you will hear cited by pharma executives when it comes to clinical trials. When you talk to sponsors about what they look for in a service provider, quality is always at or near the top of the list.

In fact, discussions about "culture of quality" are pervasive in the industry, and it's rare to attend a show or conference where this is not a popular topic of discussion. Where we may run into some disagreement is on how to best measure the level of quality in a clinical trial.

A few months ago when I decided to produce an article on measuring quality in clinical trials, the first person I turned to was Michael Howley. He has authored or co-authored several papers on the topic and has appeared in Outsourced Pharma, Clinical Leader, and *Applied Clinical Trials*. Howley has a B.S. in biology, an MBA, a Ph.D. in business administration, and currently serves as associate clinical professor in the LeBow College of Business at Drexel University. His passion is measuring quality in trials, and if he is right, you are probably doing it all wrong.

The way you measure the quality of a product is vastly different from how you would measure the quality of a service. I would certainly not measure the quality of a car I bought the same way I would measure the quality of a visit to my doctor. Unfortunately, many pharma companies may be guilty of making that mistake.

IF YOU'RE MEASURING QUALITY, YOU'RE PROBABLY NOT DOING IT RIGHT

Howley's research and experience in this space have led him to believe that there is a right and a wrong way to measure the quality sponsors are getting from a CRO. "Clinical trials are very different from manufacturing," says Howley. "In the pharma industry, most companies are manufacturers of a pill, but the clinical trial is a service. Assessing the quality of a service from a CRO must be done differently than assessing the quality of your CMO. That is the message I am trying to get out to companies. They need to think about quality differently because what they are currently doing is not working."

There is a science that has developed over the last 30 years on how to measure quality in a service industry. The methodology has been successfully applied in other industries, with great improvements in efficiency, productivity, and reduced costs.

The process of developing measures to assess service quality in trials is well established. Still, Howley notes companies are free to develop their own. When developing an assessment, Howley recommends you:

- Define what you are measuring
- Decide what specific items will be measured (cost, productivity, reliability, etc.)
- Assess the validity and reliability of what you're measuring
- Link what you're measuring to the overall quality of the trial

"I have found that pharma performs well on the first two steps," says Howley.

"They do a pretty good job defining what needs to be measured, and an amazing job identifying items for what they want to measure. Where pharma companies stumble is on the last two steps. Companies do well when collaborating with each other, but do poorly when collaborating with statisticians and psychometricians."

When performing the first two steps, sponsors might end up with 300 or 400 different measures, and decide to collect data on all of them. They then have to benchmark all of those metrics and then spend millions on a dashboard to tell them how they're performing against the averages. According to Howley, they are spending millions on software to perform 1940s-type statistics. "They are taking averages and comparing them to the mean," he says. "I tell them we can do better than that."

METRICS ARE IMPORTANT, NOT RANKINGS

In conducting his research and the findings, Howley is quick to point out his focus is on monitoring, not producing rankings. In fact, he notes companies would refuse to share their data if they knew it would result in rankings. He also believes rankings would do nothing to improve the level of quality in trials.

By now you may be wondering why do all this work if not for the rankings. Howley's hope is to be able to perform predictive analytics. "Our focus should be on monitoring the trial as it unfolds, looking at leading indicators that may eventually lead to degradation in quality," he says. "We want to try and identify quality issues before the whole trial goes off the tracks."

In the future, if a CRO receives an RFP and wants to bid on a trial, Howley's research would allow the CRO to predict the quality of its trial. "Based on the data from 10,000 trials that we have in our database, we could predict what that final outcome would be," he states. "While that may sound futuristic, it's exactly what we do today in many other areas, including academia."

Howley notes this is exactly what many districts are using to try and evaluate teachers. "Schools are using a value-added measurement system," he says. "Given all of the variables of a class (socio-economic status, past performance on tests, etc.), administrators can predict what students will learn. This is how you get to the essence of performance, not by comparing a class to an industry average. What if the whole industry is below average? That statistic really doesn't tell you anything. In clinical trials, a CRO could find itself in a situation where it is above average, but still underperforming."

MEASURING THE QUALITY

It's the customer who always determines service quality. In pharma, that is the drug sponsor. When a trial is outsourced, the sponsor assigns functional area executives to oversee specific areas of the trial. His measurement strategy has those managers evaluate how the CRO performed on areas they directly oversee. Some of the questions they could be asked are:

- How did the project manager perform?
- How was their general knowledge?
- How was their knowledge of your specific trial?
- How was their GCP and regulatory knowledge?

If he was attempting to evaluate recruitment, he might ask:

- How well did they do enrolling patients?
- How did they do on first and last patient in?
- How did they perform in regard to keeping you informed on how enrollment was progressing?
- How did they perform in enrolling patients who met your criteria?
- How did they perform at retaining patients once they were enrolled?

"Those are informative questions that will provide more value than asking the number of days to enroll a patient," says Howley. "Days to enroll is a common metric because sponsors believe it is a reliable statistic. I don't agree that it is. Are people going to go back and look in their calendar for the exact date they started enrolling and then count forward? Even if you know it took 73 days to enroll a patient, is that good or bad? For a pediatric oncology trial, you would be a rock star. For an eczema trial, it's terrible. But you see the problem here: Any metric whose meaning depends on the individual context inevitably lacks validity."

"Companies do well when collaborating with each other, but do poorly when collaborating with statisticians and psychometricians."

MICHAEL HOWLEY, PH.D.
Associate Clinical Professor in the LeBow College of Business at Drexel University

The industry is still a long way from adopting uniform standards on quality, but Howley believes we are moving in the right direction. Sponsors are beginning to see the value in monitoring trials for signs of trouble, and increased access to data will help researchers like him provide better information to sponsors and CROs. "Sponsors will be able to find CROs that are predicted to do well in the types of studies they are conducting and at the same time, these predictive models could help CROs focus on the types of trials where they are most likely to succeed," adds Howley. "We hope this will be a win for both sides."

Vendor Selection For Small Sponsors: An Approach That Works

KATIE MCCARTHY & CONNACHT PETERSON

The number of small biotech and pharma companies continues to increase and, predictably, outsourcing across the industry is on the rise. Finding the right external vendor is a critical challenge for any sponsor company, and it can be especially challenging for a small sponsor.

Small sponsors are faced with unique challenges, including smaller-scale trials, limited budgets, fewer personnel, and small pipelines that depend on the success of the lead program. Small sponsors must compete with companies that have multiple programs and trials, more robust budgets, and large in-house teams all vying for top-quality resources from CROs and other vendors. Most life sciences companies will elect to outsource at some point, so how does a small sponsor go about finding a vendor that is right for them? Through our work with dozens of small sponsors, we have refined several approaches to support selection of the *right* high-quality vendor.

THE CHALLENGES AND NEEDS OF SMALL SPONSORS WHEN WORKING WITH CROs AND VENDORS

Small sponsors have different constraints when outsourcing. They have limited employees wearing many hats who may not be expert vendor managers. Some of these companies may even lack people or processes to select and qualify vendors. Decision making is critical for any company, but for a small sponsor, every decision can feel like it's a make-or-break choice for the company — a wrong vendor decision could have future implications for the company's success or failure. Often there are executives from the company involved who are new to the nuances of clinical development, but because the decision is so pivotal, will insist on being involved at all stages. This adds complexity and must be recognized and accommodated by all parties, and there often needs to be executive-level involvement by the CRO from day one. The funding available to small sponsors is often sparse, tightly budgeted, or unpredictable, and every dollar must be carefully managed.

3 KEY STEPS FOR VENDOR SELECTION

We have found an effective process that works when it comes to selecting the best vendor for a small sponsor company. All involved must first agree on three key things:

- the **process** used for selection
- the **criteria** to select the vendor
- the **decision** of who has input and who makes the final determination

Making decisions around these key pieces in advance of starting the vendor selection process may seem both obvious and tedious, but doing so will help to lay the groundwork for successful management of a high-quality process.

The Process

Selection should start with identification of qualified vendors — a complex task even for veterans. Although we have a wide network of CROs and vendors with whom we've worked, the landscape changes and evolves constantly so we still make a point to reach out to our colleagues for timely referrals or recommendations. Vendors and teams change quickly in this industry so it's best to have up-to-date reviews across multiple sources. Once a list of potential vendors is compiled, the rest of the traditional process applies: request for proposal (RFP), proposal review and analysis period (with open and honest communication), bid defense meetings, due diligence capabilities audits, negotiation, scope work, final selection, and transfer of obligations. The most critical but subjective goal at this stage is to identify a short list with the right fit from both a scale and cultural perspective.

The Criteria

In order to swiftly move through the vendor selection process, the team must agree on the selection criteria before the process begins. This must be managed within the sponsor team and clear expectations aligned internally before focusing outwards. Although the detailed criteria will be protocol-specific, CRO- and vendor-selection criteria should be based on three key areas:

1. **VENDOR CREDIBILITY:** experience with small sponsors and programs, proven expertise in the desired therapeutic area, expertise in the geographic area, and specific technical experience

2. **VENDOR CAPABILITY:** customized planning and feedback on the protocol, plan, and timelines; right-sized technology and reports; issue identification and resolution; team chemistry; strategic fit; and CRO executive involvement on a routine basis

3. **BUDGET:** clear and direct methods for budget management, straightforward process for handling budget or schedule changes, fair prices for services, willingness to negotiate

Additionally, small sponsors must maintain open and honest communication with potential CROs or vendors throughout the process. Honest communication about existing gaps within the sponsor company should be shared to ensure these gaps are adequately filled by the potential vendor.

The Decision

Prior to making a final choice, the sponsor company must determine who will participate in the vendor selection process and how the final decision will be made. Will all team members individually rate each vendor based on the agreed-upon criteria? Will the team make the final decision together democratically? Will the team make a recommendation to a single decision maker? There are many ways to get to a decision, but how the final selection will be decided must be determined before the process even begins.

THE RELATIONSHIP MUST BE A PARTNERSHIP

Carefully selecting the right CRO or vendor is critical for small-sponsor success. Following our selection process, the criteria to select the vendor, and the decision of who has input and who makes the final determination will ensure selection of the right high-quality vendor. This does not mean there won't be a critical need to have close management and oversight of that vendor, but alignment at the beginning can help. All parties at a sponsor company can more effectively work together to identify the best process to select a vendor and act on it if expectations are aligned at the outset. The relationship must be a partnership from the earliest stages, so approach it with that level of care and attention! L

Katie McCarthy is managing director at Halloran Consulting Group. She leads the company's emerging biotechnology and pharmaceutical practice area. She has 18+ years of drug development experience.

Connacht Peterson is senior consultant at Halloran Consulting Group. She has 11+ years of clinical development experience with a focus on clinical operations and development and global project management.

Small Pharma And Large CROs: Considerations For Partnering

ED MISETA Executive Editor @OutsourcedPharm

When it comes to selecting a CRO, pharma companies have a lot of decisions to make. Do you go with a CRO that has experience and expertise in your study? How should you rank their proficiency in critical areas such as regulatory, quality, and timeliness? Do you go with a CRO you have familiarity with or try something new?

All are noteworthy considerations, but if you're a small pharma or biotech company, you have an additional decision to make: what size CRO do you go with?

Linda Strause, Ph.D., principal and founder of Strategic Clinical Consultants, has helped many small firms navigate through this decision. A large CRO can bring a lot to the table for a small pharma company. They generally have a number of silos dedicated to every component of a clinical trial, including study start-up, clinical operations, risk-based monitoring, statistics, data management, and proposals. Unfortunately dealing with a large CRO can also have some drawbacks. One of the first drawbacks is getting them to understand the mindset and capabilities of a small company.

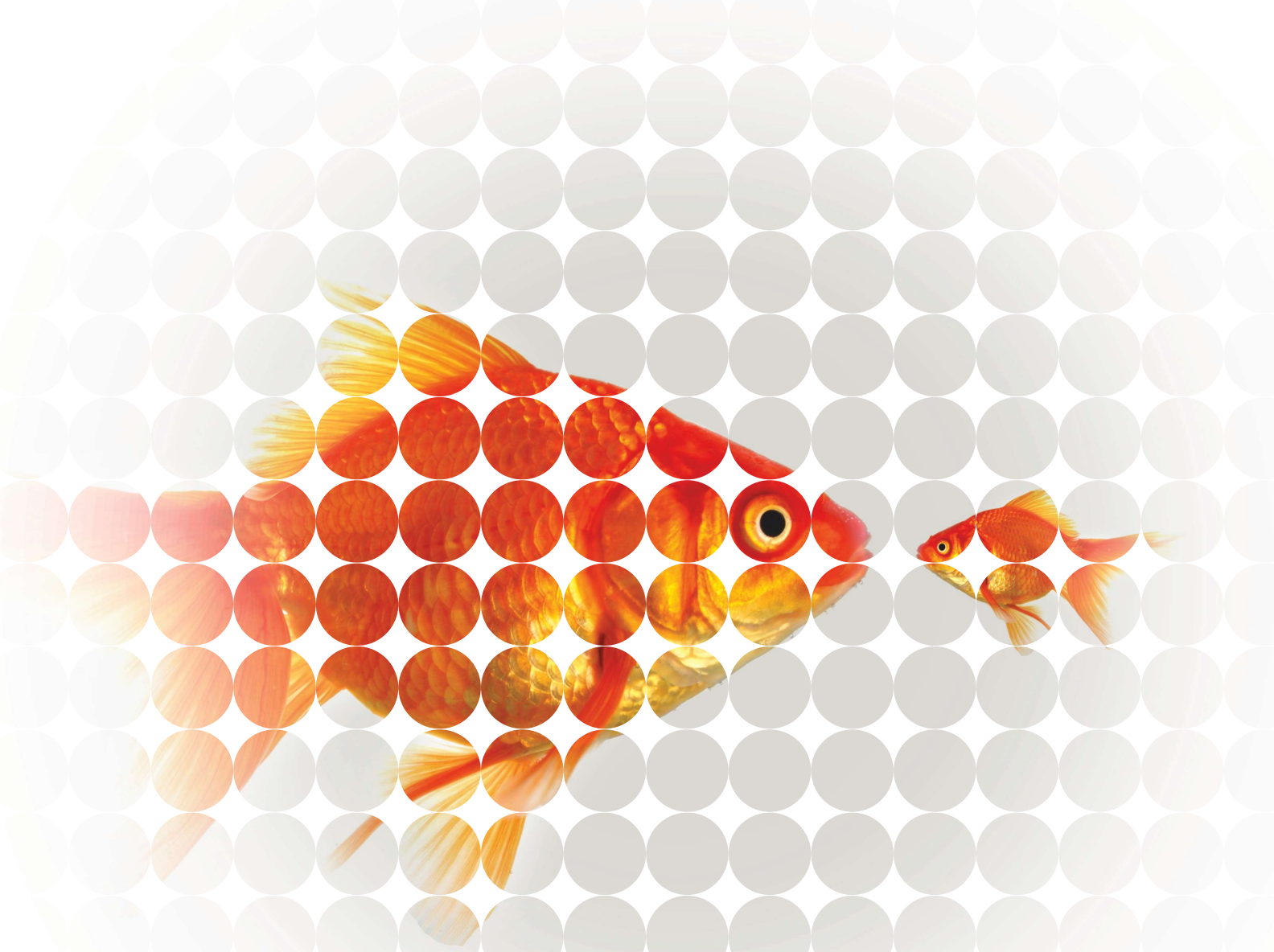
"I recently had the opportunity to deal with a large CRO," says Strause. "We had an introductory phone call to get to know each other. The folks with the CRO all introduced themselves. When it was my turn to present my small company, I went around the table, introducing the CEO, a couple of vice presidents, and myself. At that point someone from the CRO asked if they would have the opportunity to meet the operations group at a later date. He didn't understand that this was it. Everyone on our team was already on the phone."

That incident upset Strause, eventually resulting in her bringing it to the attention of senior management at the CRO. What was clear to her was that larger CROs needed to do their homework better prior to sitting down for a kick-off meeting.

"When dealing with a virtual company, you need to know something about them going in," she notes. "There are a lot of things those companies don't do. Throughout that meeting, we were asked a lot of questions about things that did not specifically apply to our protocol. We received budget spreadsheets that included Asia, Europe, and other places around the world, when the company was doing a small study in North America. If someone is going to take time from several executives to hold a meeting, they should first determine if it is even necessary. If they had done their homework and understood the company, a lot of time could have been saved. Presentations should always be personalized for the company sitting at the table."

Strause notes finances are also very important to her. Small virtual firms do not have the budgets of many larger companies. When working with large CROs she gets tracking of budgeted versus actual costs but projecting expenses into the months ahead would help to manage limited financial resources.

"Some CROs think they can pass along any costs they incur," she says. "I am the client and I have to pay that bill. I am the one who gets stuck with it. I have a bucket of money with nothing going in but a lot coming out. I have to manage that money very differently than a large pharma or biotech company. It is vital for the large CRO to work with me and help me to make intelligent decisions and projections."



ONE SIZE DOES NOT FIT ALL.

Your clinical research program is different – because it's yours. To make the most of it, you need a CRO who brings more to the table than a predetermined process. You need a partner who starts by understanding your situation and learning about your exact specifications – experienced professionals who customize engagements so the services you get are perfectly matched to your vision and goals. That's our approach. Let's talk about yours.

LET'S TALK

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"In the drug development industry an investigational site may be a top enroller in one study and enroll poorly in another even if they are in the same therapeutic area."

LINDA STRAUSE, PH.D.
Principal and Founder of
Strategic Clinical Consultants

WHY GO LARGE?

If going with a large CRO has both benefits and drawbacks, how do you decide if a large CRO is the right fit for your company? Strause notes that discussions usually balance experience with culture.

"Experience and technology are generally the drivers I see at work," she says. "Technology is always important, and you want to make sure the CRO you select will have the proper technologies in house. I also see companies trying to rely too much on past experience. I don't necessarily agree that is the best approach, and I think companies can sometimes rely too much on the belief that if a company has done it before, they can do it again. In the drug development industry an investigational site may be a top enroller in one study and enroll poorly in another even if they are in the same therapeutic area. The same is often true of a CRO. There are too many variables that can change the outcome."

Other parameters that influence decisions include financial stability and reputation of a CRO. A virtual company is very aware of financial instability and requires a fiscally strong CRO as a partner. Strause was forced to manage the impact on a pivotal oncology study when one of the CROs filed bankruptcy. It was very challenging and difficult. The CRO's reputation may also influence the company's decision as having a well-known CRO may influence future partnerships or sale of the company.

"I don't play in the funding space so I don't know if that is true or not, but my belief has always been that the data is good or it is bad. Neither the CRO nor the sponsor can make a product work. Only the data can tell us," she states.

RESOURCE ALLOCATION OR BAIT-AND-SWITCH?

One of the most important considerations for a small company working with a large CRO is knowing who will perform the work on your study. Oftentimes a sponsor will be told that one team or individual will do the work, only to have that change as soon as the study is underway. While some sponsors will refer to that situation as bait-and-switch, on this topic Strause comes to the defense of the CROs.

"I don't think it is bait-and-switch," she says, "and I do not think it is intentional. When a big CRO first comes in they will naturally bring their A-team. I have certainly been in situations where we get three months into a contract and suddenly I am dealing with a new project manager, but it's not bait-and-switch. I believe this situation has more to do with resource leveling and allocation. A large CRO deals with numerous clients, large and small, and each wants the best of the best. Everyone wants the A-team working on their project, but even in a large company, that is simply not always possible."

Strause is currently working with a midsize CRO that she believes is taking a unique approach and making significant effort to meet the needs of the client. The business development person who made the sale continues to have a weekly call with the director of clinical operations. With many of the larger CROs she has worked with, unless she has a complaint, she will never again hear from the business development contact. That type of personal attention can go a long way towards alleviating the unhappiness caused by a change in project manager.

WHAT TO DO WHEN THINGS GO WRONG

No matter how well you vet your CRO, sometimes things will still not go as planned. That will happen with large CROs as well as small. Of course, how you approach the situation will determine your success at getting any situation resolved.

If a study is not going according to plan, Strause recommends going to the business development person or higher. "Rarely do I believe these situations to be the fault of the project manager," she says. "At the same time, the person who will benefit the most from the client being happy is that BD person. Unfortunately, what will normally happen is the project manager will simply be moved to another study. That is just the way things work in this world."

There was only one time when Strause came close to removing a large CRO in mid-study. This was early on in the project, but she believes if you're going to make a move, it's better to do it sooner rather than later. She recommends doing it only if you truly feel you have nowhere left to turn. Still, knowing when to pull the plug is a difficult challenge.

"That's the most difficult question to answer," she says. "To start, I think people have to be able to admit they made a mistake. That is difficult in and of itself. It was the hardest thing I ever had to do and I dreaded having to make that decision. I am all about metrics. If I see we are behind on the timeline and things are not being done correctly, I will go to the highest level executives I can reach. I would even go so far as to request bi-weekly calls with the clinical project manager and their line manager and that person's line manager. I feel you need to go up at least three levels to get to the directors and VPs of clinical operations. They will do everything in their power to make you happy, but if things are still not going as they should, you need to cut them loose. Sometimes companies are just not a match for each other."

Industry Leaders by Market Segment
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Company Profiles
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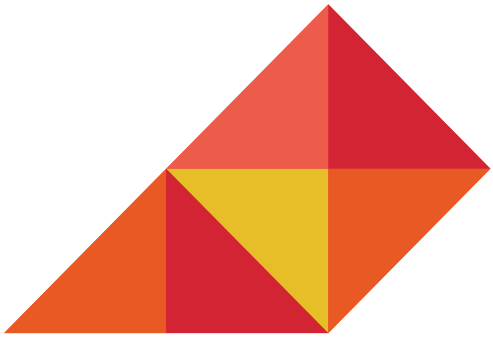


CRO LEADERSHIP AWARDS 2015

THE PHILOSOPHY OF THE AWARDS

Life Science Leader's readership of pharmaceutical and biopharmaceutical executives have told us about their struggles in vetting CRO partners. In response, *Life Science Leader* developed the CRO Leadership Awards based on industry research conducted by Nice Insight. The awards incorporate common filters used by pharma companies to vet CROs with the added filter of peer feedback. This helps pharma and biopharma companies focus on potential CRO partners who can handle their projects and are considered reputable in the industry.

Nice Insight combines surveying thousands of industry executives with other key analyses to serve both partnering groups, and facilitate better overall outsourcing collaborations. Since there are significant differences in how different types of companies approach outsourcing, research respondents are assigned to one of five categories: big pharma, midsize & specialty pharma, emerging pharma, biotech, and emerging biotech. Scores are assessed by each company type in five perception categories: Innovation, Productivity, Quality, Regulatory, and Reliability. Companies achieving top-10 percentile perception scores are recognized for their achievements with a 2015 CRO Leadership Award.

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

PRESENTED BY: Life Science Leader

RESEARCH CONDUCTED BY: niceinsight
A That's Nice Brand

When Selecting Partners, Survey Respondents Ranked

QUALITY

as their Number One Priority.

RANK OF INDUSTRY DRIVERS (THERE WAS A TIE FOR FOURTH PLACE)

1 Quality
2 Reliability
3 Productivity
4 Innovation
4 Regulatory

WHAT ARE THE AWARDS?

Companies achieving top 10 percentile perception scores in the areas of Innovation, Productivity, Quality, Regulatory, and Reliability are recognized for their achievement. These categories were defined for the research participants as follows:

QUALITY AWARD Business is reputable and compliant

BIG PHARMA
BASi
Clinlogix
Eurofins Lancaster Laboratories, Inc.
PAREXEL International

MID-SIZED/SPECIALTY PHARMA
Algorithme Pharma
Eurofins Lancaster Laboratories, Inc.
MedSource
MicroConstants
SCYNEXIS, Inc.

EMERGING PHARMA
Algorithme Pharma
BASi
Charles River
Frontage Laboratories
GenScript
Spaulding Clinical Research, LLC
Vince & Associates Clinical Research

BIOTECH
Clinlogix
Frontage Laboratories
PAREXEL International
PRA Health Sciences

EMERGING BIOTECH
Chiltern
MicroConstants
PPD
Quanticate
Surpass, Inc.
Worldwide Clinical Trials

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

BIG PHARMA
Acceleration Laboratory Services
BASi
InVentiv Health
Quintiles
Tandem Labs, now Covance Inc.

MID-SIZED/SPECIALTY PHARMA
Accell Clinical Research
Eurofins Lancaster Laboratories, Inc.
LabCorp Clinical Trials, now Covance Inc.
MPI Research
SanaClis s.r.o.

EMERGING PHARMA
Algorithme Pharma
Clinlogix
Covance Inc.
GenScript
MedSource
SynteractHCR

BIOTECH
JRF Global
Quest Diagnostics Clinical Trials

EMERGING BIOTECH
Chiltern
Clinlogix
PPD

2015 Average number of services outsourced by company type (projected)

7.4

2015 Annual Outsourcing Expenditure (projected)

Less than 10 million USD per year	10 to 50 million USD per year	50+ million USD per year
16%	**62%**	**23%**

Average number of methods used to select an outsourcing partner

3

Top 3 methods used to select an outsourcing partner

1. Consultants
2. Referrals
3. Trade Show/Events

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

BIG PHARMA
InVentiv Health
Rho
Tandem Labs, now Covance Inc.

MID-SIZED/SPECIALTY PHARMA
Eurofins Lancaster Laboratories, Inc.
LabCorp Clinical Trials, now Covance Inc.
MicroConstants
Quanticate
Theorem Clinical Research

EMERGING PHARMA
Algorithme Pharma
MedSource
SynteractHCR
Theorem Clinical Research

BIOTECH
BASi
Chiltern
Frontage Laboratories
JRF Global
PRA Health Sciences

EMERGING BIOTECH
QPS Holdings, LLC
Vince & Associates
Clinical Research
Worldwide Clinical Trials

INNOVATION AWARD Business will deliver on agreed objectives

BIG PHARMA
ABC Laboratories
BASi
Clinlogix
InVentiv Health
Rho
Spaulding Clinical Research, LLC

MID-SIZED/SPECIALTY PHARMA
Chiltern
Eurofins Lancaster Laboratories, Inc.
Frontage Laboratories
ICON plc
Quest Diagnostics Clinical Trials
Seventh Wave Laboratories

EMERGING PHARMA
BASi
Charles River
MedSource
MicroConstants
Spaulding Clinical Research, LLC
SynteractHCR
Vince & Associates
Clinical Research

BIOTECH
Algorithme Pharma
Vince & Associates
Clinical Research

EMERGING BIOTECH
Chiltern
Clinlogix
Quanticate
Rho
Vince & Associates
Clinical Research
Worldwide Clinical Trials

REGULATORY AWARD Business will meet all project milestones and timelines

BIG PHARMA
ABC Laboratories
BASi
Clinlogix

MID-SIZED/SPECIALTY PHARMA
BASi
Chiltern
MicroConstants
Quanticate

EMERGING PHARMA
Algorithme Pharma
MedSource
Rho
SynteractHCR

BIOTECH
Clinlogix
JRF Global
MPI Research
PRA Health Sciences

EMERGING BIOTECH
MicroConstants
Quanticate
Surpass, Inc.
Vince & Associates
Clinical Research

CATEGORIES WON

ABC Laboratories

Columbia, MO
www.abclabs.com

+1 573 777 6000
Eric Hoffman
hoffmane@abclabs.com
Key locations: Columbia, MO

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

MAIN SERVICE AREAS:
Lab

SERVICES & CAPABILITIES: CMC analytical support and QC for API and drug product under CGMP, E&L, trace analysis, biopharmaceutical bioanalytical method development and sample testing, radiolabeling and custom synthesis, environmental assessments, development strategy/consulting

THERAPEUTIC AREAS: ABC has worked with virtually every class and type of compound, across most indications and all common delivery systems. We have contributed data to and drafted sections of IND, NDA, and ANDA submissions for dozens of commercial products.

JOHN BUCKSATH
president & CEO

"ABC is honored to have been recognized by industry three years in a row. It is rewarding to see our investments aimed at delivering "better insight" and "better outcomes" to our clients are earning our organization a reputation for excellence."

CATEGORIES WON

Acceleration Laboratory Services, Inc

Lee's Summit, MO
accelerationkc.com

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

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

MAIN SERVICE AREAS:
Preclinical, Full Service Clinical

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

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

BRENT TAYLOR
CEO

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

CATEGORIES WON

Accell Clinical Research

Culpeper, VA
www.accellclinical.com

+1 540 321 4051 or +7 812 332 1420
Julia Kondakov
bd@accellclinical.com
Key locations: U.S.A., St.Petersburg, Russia (clinical headquarters managing studies in Russia, Ukraine, Baltic States, Bulgaria, Romania, and other Eastern European countries) and Ukraine.

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: Clinical trials in Russia and Eastern Europe, fast patient recruitment, deliver high-quality data, and service packages & project models adjusted exactly to client needs.

THERAPEUTIC AREAS: Our leading indications are oncology, cardiovascular diseases, endocrinology, CNS diseases, and infectious diseases.

JULIA KONDAKOV
director, business development/ managing member

"This is a very positive feedback for us. For years we have been building trust relationships with our clients and mutual understanding with research centers. We are happy to see that these efforts not only bring high-quality data for our clients and better medications to more patients, but are also recognized publicly."

CATEGORIES WON

Algorithme Pharma

Laval, Québec, Canada
www.algopharm.com

+1 450 973 6077
Catherine Konidas
ckonidas@algopharm.com

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

MAIN SERVICE AREAS:
Lab, Full Service Clinical

SERVICES & CAPABILITIES: Full-service offering focused on early stage clinical development: design and conduct of Phase I/IIa trials, large and small molecule bioanalysis, data management, biostatistics, regulatory support, clinical pharmacology, and project management

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

CHRIS PERKIN
president & CEO

"Our mission has always been to provide the highest quality early stage clinical development solutions, while exceeding our customers' expectations with personalized and timely service. These awards recognize and validate the efforts our employees put in on a daily basis to achieve our goal. To be recognized by our clients in such a way is both rewarding and a phenomenal success story for us."

CATEGORIES WON

Charles River

Wilmington, MA
www.criver.com

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

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

MAIN SERVICE AREAS:
Preclinical, Lab

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

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

JAMES C. FOSTER
chairman, president and CEO

"I am pleased that our clients recognize Charles River's industry leadership with this award. Our portfolio is the strongest it has ever been, with the ability to support clients from target discovery through preclinical development. We have deep client relationships, where we are a respected and trusted partner; a streamlined organization, with the flexibility to respond to a changing industry and client requirements; and employees who are committed to providing exceptional service."

CATEGORIES WON

Chiltern

Slough, Berkshire, United Kingdom
www.chiltern.com

+1 910 338 4760 or +44 1753 512 000
Nicholas Spittal
lets.talk@chiltern.com
Key locations: United States, United Kingdom, Western Europe, Central and Eastern Europe, Latin America, Asia-Pacific, MENA

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: Project management, clinical monitoring, regulatory affairs, medical monitoring, data management, biostatistics, pharmacovigilance, medical writing, activate study startup, eClinical, database programming, resourcing, QA, late phase, functional service provider, and interactive response technology

THERAPEUTIC AREAS: Oncology, anti-infectives, vaccines, ophthalmology, dermatology, respiratory, rheumatology, inflammation, hematology, and gastroenterology

DR. JIM ESINHART
CEO

"Chiltern's approach is one of leading by listening and then applying our experience and skill to develop a customized solution. We work on a flexible platform where our employees are encouraged to be creative and service-oriented to meet client requirements. Chiltern creates an engagement that is truly unique to customer requirements; be that an individual study, a full clinical program, a single CRA, or an entire biometrics function. Our services are 'Designed Around You.'"

CATEGORIES WON

Clinlogix

Ambler, PA
www.clinlogix.com

+ 1 215 855 9054
Mike O'Gorman
mogorman@clinlogix.com
Key locations: Ambler, PA, United States.; Medellin, Colombia; Germany

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: Project management, clinical monitoring, data management, statistics, safety, site selection, site management, medical writing, regulatory services, and more

THERAPEUTIC AREAS: Cardiovascular, endocrine, anti-infective, hematology, oncology, central nervous, ophthalmology system, respiratory, dermatology, vaccines, women's health, gastrointestinal, and more

JEANMARIE MARKHAM
CEO

"Clinlogix provides scientific leadership delivered with operational excellence to the life sciences industry. Over fifteen years of experience, Clinlogix continues to place a high value on communications, training, and teamwork. We listen to our clients and provide them with outstanding responsiveness and service. Entrusted with all critical elements of a study, Clinlogix's expertise assists our clients to set realistic objectives in terms of study design and safety to ensure success."

CATEGORIES WON

Covance Inc.

Princeton, NJ
www.covance.com

+1 609 452 4440 or +00 800 2682 2682
Jared Freedberg
jared.freedberg@covance.com
Key locations: Brazil, China, Germany, Russia, Singapore, Switzerland, United Kingdom, United States

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

MAIN SERVICE AREAS:
Lab, Preclinical, Full Service Clinical

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

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

JOE HERRING
CEO

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

CATEGORIES WON

LabCorp Clinical Trials, now Covance Inc.

Cranford, NJ
www.covance.com

+1 877 788 8861
Josh Goldsmith, Ph.D.
Josh.Goldsmith@covance.com
Key locations: Brentwood, TN, Cranford, NJ, Hollywood, FL, Los Angeles, CA, Seattle, WA, United States; Mechelen, Belgium; Singapore; Beijing, China

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

MAIN SERVICE AREAS:
Lab

SERVICES & CAPABILITIES: Advanced flow cytometry/genomics, bioanalytical, biorepository, coagulation, companion diagnostics, cytogenetics, early phase, endocrinology, FISH, immunohistochemistry, infectious disease/viral genotyping, in-vitro diagnostic device trials, molecular genetics, PBMC processing, pharmacogenetics, safety testing, and tumor markers

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

STEVE ANDERSON, PH.D.
senior VP, LabCorp;
CSO, Covance Inc

"LabCorp Clinical Trials is honored to receive this special recognition from our clients in the categories of reliability and productivity. Our organization is committed to providing exemplary quality in every aspect of our business. We focus not only on the service we provide today, but also on the new and innovative solutions we will provide our clients tomorrow. We appreciate your trust and will work tirelessly to keep it."

COVANCE SOLUTIONS MADE REAL®

CATEGORIES WON

Tandem Labs, now Covance Inc.

Salt Lake City, UT
www.covance.com

+1 801 293 2400
Todd Grosshandler
todd.grosshandler@covance.com
Key locations: Durham, NC; Salt Lake City, UT; West Trenton, NJ

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

MAIN SERVICE AREAS:
Lab

SERVICES & CAPABILITIES: LC-MS/MS & immunoanalytical services - small/large molecule, discovery, preclinical (GLP), clinical, non-proprietary assays; biomarkers - proprietary/custom assays, CLIA/GLP-compliant, multiple platforms; specialized LC-MS/MS (proteins, oligonucleotides) and immunoanalytical (immunogenicity, cell-based assays, vaccines)

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

JAMES WILFAHRT
vice president & general manager

"The expertise and responsiveness of our staff is directly tied to our ability to meet and exceed the expectations of our pharmaceutical clients. We focus exclusively on bioanalytical services, building strong relationships with clients that allow us to develop programs that meet even the most difficult challenges. Bringing new drugs to market is more challenging than ever in today's environment, so we take great pride in doing everything we can to make your job easier."

eurofins | Lancaster Laboratories

CATEGORIES WON

Eurofins Lancaster Laboratories, Inc.

Lancaster, PA
www.EurofinsLancasterLabs.com

+1 717 656 2300
Michael McDowell
MichaelMcDowell@eurofinsus.com
Key locations: Lancaster, PA, Portage, MI, United States; Clogherane, Dungarvan Co. Waterford, Ireland; Munich, Germany

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

MAIN SERVICE AREAS:
Lab

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

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

DR. TIMOTHY OOSTDYK
president

"We are delighted that Eurofins Lancaster Laboratories has been recognized with the CRO Leadership Award for the third year in a row. We know that quality, reliability, productivity, and innovation are among the most important criteria for our clients when choosing a contract lab, and so this recognition in these categories is very gratifying. We are extremely proud to serve our customers every day as a global leader in laboratory services for the bio/pharmaceutical industry."

FRONTAGE

CATEGORIES WON

Frontage Laboratories

Exton, PA
www.frontagelab.com

+1 610 232 0100
Azhar Kalim
akalim@frontagelab.com
Key locations: Changchun, Shanghai, Suzhou, Tianjin, Jirin, China; Exton, PA, Hackensack, NJ, Secausus, NJ, Somerset, NJ, United States

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

MAIN SERVICE AREAS:
Lab, Preclinical, Full Service Clinical

SERVICES & CAPABILITIES: Bioanalysis, preclinical DMPK, clinical and bioequivalence studies, API and product development with analytical support spanning discovery through late-stage clinical trials. Frontage supports clients with NDA, ANDA, and 505.b.2 submissions

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

DR. SONG LI
CEO

"In a highly collaborative setting, we are committed to operate as an extension of clients' resources. Our team consists of dedicated scientists and skilled professionals across multiple business units. This combination of technical expertise and focus on clients gives us the ability to maneuver the complex drug development process in a cost-effective manner. It is an honor to be recognized again for the prestigious CRO Leadership Awards for our innovation, productivity, and commitment to quality."

CATEGORIES WON

GenScript

Piscataway, NJ
www.genscript.com

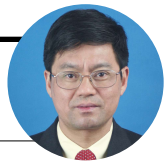
+1 732 885 9188
Gene Dove
gene.dove@genscript.com
Key locations: Piscataway, NJ, United States; Tokyo, Japan; Nanjing, China; Amsterdam, Netherlands

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical
Formulated Drug Production: Dosage Form Development

MAIN SERVICE AREAS:
Lab, Preclinical

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

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



FRANK ZHANG
CEO

"We are delighted to receive the CRO Leadership Awards two years in a row. GenScript's team members are the reason for our success. We have professional teams for all aspects of customer interaction including R&D, S&M, project management, and customer service. The fact that our customer's voted us as the best for quality and reliability among all service providers speaks volumes about the fruitful outcome of our efforts."

CATEGORIES WON

ICON plc

Dublin, Ireland
www.iconplc.com

+353 1 2912000
Paul Colombo
info@iconplc.com
Key locations: Dublin, Ireland; Philadelphia, PA, Farmingdale, NY, San Antonio, TX, United States; Frankfurt, Germany; Tokyo, Japan; Chennai, India; Beijing, China

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

MAIN SERVICE AREAS:
Lab, Full Service Clinical

SERVICES & CAPABILITIES: Protocol design, biomarker services, medical and safety services, health economics and outcomes research, adaptive trial design, biostatistics, patient recruitment, medical imaging, laboratory services, contract resourcing, consulting, market access, and patient-centric monitoring

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

TOM O'LEARY
chief information officer

"We are proud to again be recognized by the industry as a leader in innovation. We have been successful in building relationships with the world's top biopharma companies because of our ability to execute and because we have been at the forefront of innovation in the design and conduct of global clinical trials. This relentless pursuit of improvement is what distinguishes ICON as a trusted and reliable partner for our customers."

CATEGORIES WON

inVentiv Health

Princeton, NJ
www.inventivhealth.com

+1 609 951 6800
Gregory Skalicky
Gregory.Skalicky@inventivhealth.com
Key locations: Ann Arbor, MI, Miami, FL, Princeton, NJ, U.S.A; Buenos Aires, Argentina; Maidenhead, United Kingdom; Quebec City, Quebec, Canada; Singapore; Zurich, Switzerland

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: Clinical development and commercialization services, therapeutically specialized capabilities for Phase I-IV clinical development, bioanalytical services, and strategic resourcing

THERAPEUTIC AREAS: inVentiv Health has expertise in virtually all therapeutic areas including cardiovascular, dermatology, endocrinology and metabolics, infectious diseases, nephrology, neuroscience, oncology, rare diseases, pain and inflammatory diseases

GREGORY SKALICKY
chief commercial officer

"inVentiv Health is proud to have been selected as a CRO Leadership Award Winner in the categories of innovation, reliability, and productivity. To have been recognized in these categories is especially gratifying given our focus on client service and client satisfaction. We are dedicated to providing the best possible support for our clients' important drug development programs and strive everyday to deliver on our shared objectives in the constant pursuit of operational excellence."

JRF GLOBAL

CATEGORIES WON

JRF Global

Valvada, Gujarat, India
www.jrfglobal.com

+91 260 6540242
Samir Pandya
bd@jrfonline.com
Key locations: India, Japan, U.K., U.S.A

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical

MAIN SERVICE AREAS:
Preclinical

SERVICES & CAPABILITIES: Mammalian toxicology, in vitro toxicity, ADME/DMPK, repeated dose inhalation, reproductive toxicity, neurotoxicity, immunotoxicity, canine research, Zebrafish discovery assays, safety pharmacology, IND/NDA/ANDA evaluations, analytical studies, bioanalyticals, ecotoxicology, environmental fate, and endocrine disruptor screening

DR. ABHAY DESHPANDE
director, global

"JRF Global offers worldwide contract research services from state-of-the-art research facilities in the U.S., U.K., India, and Japan. We are dedicated to ensuring on-time study completion, timely updates, and excellence through professional program management for our clients; for us, 'The customer always comes first.' Winning at the 2015 CRO Leadership awards is wonderful validation that our clients appreciate our efforts and value. We hope to be permanent fixtures on future lists as well!"

MEDSOURCE
Taking Relationships as Seriously as Science

CATEGORIES WON

MedSource

Houston, TX
www.medsource.com

+1 281 286 2003
Matthew Wagener
mwagener@medsource.com
Key locations: Houston, TX; Raleigh, NC; San Diego, CA; Boston, MA (3Q 2015)

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: Phase 1 to 4 project management, monitoring, regulatory affairs, drug development, safety/pharmacovigilance, statistical analysis, data management, medical writing, protocol development, strategic program development, DSMBs, central lab, translations, risk based monitoring, and central imaging

THERAPEUTIC AREAS: Oncology, CNS, infectious disease, hematology, cardiovascular disease, transplant, nephrology/urology, gastrointestinal disorders, pain management, devices, respiratory diseases, endocrinology, rare diseases and disorders

ERIC LUND
president & CEO

"MedSource's strong ranking in this global industry survey is a testament to the depth of our clinical expertise, the dedication of our employees, and the confidence shown by our clients. We pride ourselves on developing lasting relationships, providing innovative solutions, being flexible, and bringing the highest level of quality to the table. MedSource is honored to be recognized as an industry leader and we owe this distinction to the efforts and commitment of our employees."

MicroConstants
REGULATED BIOANALYSIS & DMPK

CATEGORIES WON

MicroConstants

San Diego, CA
www.microconstants.com

+1 858 652 4600
Ron Shevock
rshevock@microconstants.com
Key locations: San Diego, CA, United States; Biejing, China

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

MAIN SERVICE AREAS:
Lab, Preclinical

SERVICES & CAPABILITIES: LC-MS/MS bioanalytical method development, validation, sample analysis for small molecules; ELISA method development, validation, sample analysis for large molecules; MSD and luminex capabilities for biomarker analysis; in vitro DMPK assays

GIL LAM
president & chief scientific officer

"MicroConstants is dedicated to becoming the recognized leader in regulated bioanalysis, drug metabolism, and pharmacokinetic analysis. We understand that the only way to achieve this goal is by providing our partners with the highest quality data, exceptional client services, state-of-art equipment, and a team of skilled professionals. We strive to meet our customers' needs, exceed expectations, and continually expand our contract research services to help advance our clients' drug discovery and development programs."

MPI Research

CATEGORIES WON

Mattawan, MI
www.mpiresearch.com

+1 269 668 3336
Ed Amat
info@mpiresearch.com
Key locations: Kalamazoo, MI; Mattawan, MI

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

MAIN SERVICE AREAS:
Preclinical, Clinical

SERVICES & CAPABILITIES: Drug safety, discovery sciences, bioanalytical and analytical solutions, surgical services and medical device evaluation, translational imaging, and clinical research services

THERAPEUTIC AREAS: Metabolic, endocrinology, ocular/otic, orthopaedic, gastrointestinal, cardiovascular, renal, neurosciences, inflammation, infectious diseases, oncology, rare or orphan genetic disorders, and stem cell therapeutics

BILL PARFET
chairman & CEO

"We are honored to receive these esteemed awards. Being identified by our industry colleagues as a reliable CRO, that operates in accordance with all regulatory guidelines and best practices, exemplifies our teams' dedication to advancing global healthcare."

PAREXEL International

CATEGORIES WON

Waltham, MA
www.PAREXEL.com

David Godwin
David.Godwin@PAREXEL.com
Key locations: The Americas, Europe/Middle East/Africa, Asia/Pacific

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: Expertise-based contract research, consulting, and technology solutions across the drug development and commercialization continuum, including drug development, regulatory consulting, clinical pharmacology, clinical trials management, medical education, and reimbursement

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

JOSEF VON RICKENBACH
chairman & CEO

"At PAREXEL, we have a comprehensive view of the clinical trial process. Our extensive experience in clinical development, our expert regulatory and commercial consulting, and our leading-edge technology equip us to help our clients bring new treatments to patients around the globe. Guided by the principles of quality, innovation, and teamwork, PAREXEL is able to help biopharmaceutical companies at every step of their drug development journey."

PPD

CATEGORIES WON

Wilmington, NC
www.ppdi.com

+1 910 251 0081
Business Development
ppdinfo@ppdi.com
Key locations: Operations in 46 countries spanning North America, Europe, Middle East, Africa, Asia-Pacific, Latin America; headquarters in Wilmington, NC

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

MAIN SERVICE AREAS:
Lab, Preclinical, Full Service Clinical

SERVICES & CAPABILITIES: Capabilities span the value chain, combining global resources with in-depth local knowledge and top scientific, medical and operational talent to drive success for a broad spectrum of clients

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

DAVID SIMMONS
chairman & CEO

"At PPD, we collaborate closely with our clients to bend the cost and time curve of drug discovery and development to deliver life-changing therapies to market more quickly and cost-effectively. Our comprehensive portfolio of services features integrated Phase I-IV and laboratory services, technology providing real-time data analytics, industry-leading patient recruitment, innovative study start-up, global capabilities, and a deep bench of scientific, medical, and operational talent."

CATEGORIES WON

PRA Health Sciences

Raleigh, NC
www.prahs.com

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

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

MAIN SERVICE AREAS:
Lab, Full Service Clinical

SERVICES & CAPABILITIES: Innovative full-service clinical and staffing solutions across all phases and therapeutic areas. Providing coverage across 80+ countries.

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

COLIN SHANNON
president & CEO

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

CATEGORIES WON

QPS Holdings, LLC

Newark, DE
www.qps.com

+ 1 512 350 2827
Livia Legg
livia.legg@qps.com
Key locations: Austria; Delaware, Florida, Missouri, North Carolina, United States; India; Taiwan; The Netherlands

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

MAIN SERVICE AREAS:
Lab, Preclinical, Full Service Clinical

SERVICES & CAPABILITIES: Small molecules, large molecules, antibody drug conjugates, oligonucleotides, elements and elemental tags, biomarkers, IND program management, ADME, neuropharmacology, toxicology, protocol writing, clinical conduct, site management and monitoring, clinical study reports

THERAPEUTIC AREAS: Alzheimer's, Parkinson's, Huntington's, depression, ALS, ADHD, T2DM, asthma, COPD, RA, psoriasis, HIV, HCV, HBV, oncology, and more

DR. BEN CHIEN
president & CEO

"I am excited and gratified that QPS employees have again been honored with a CRO Leadership Award for delivering exceptional service in discovery, preclinical, and clinical drug development. Through frequent, important upgrades to our resources and capabilities, vigilant and earnest customer service, and deep dedication to scientific excellence, we offer powerful support our customers can rely on. A fledgling worldwide leader in contract research, QPS has emerged as both valued collaborator and compassionate employer."

CATEGORIES WON

Quanticate

Hitchin, Hertfordshire, United Kingdom
www.quanticate.com

+44 1462 440 084
Daniel Chapple
Daniel.Chapple@quanticate.com
Key locations: United Kingdom, United States, India, South Africa, Poland

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: Management, analysis, and reporting of data from clinical trials and post-marketing surveillance; services include data management, biostatistics, programming, medical writing, pharmacovigilance, and consultancy.

THERAPEUTIC AREAS: Experience across all therapeutics areas

DAVID UNDERWOOD
CEO & chairman

"We are delighted that Quanticate has been recognized for quality, reliability, regulatory, productivity, and innovation for a second year running. I would like to thank the dedication and determination of our employees in consistently performing above and beyond to enable Quanticate to be recognized. Our position as a leading global data-focused CRO enables us to provide experience and reassurance as well as high-quality deliverables to our customers."

Quest Diagnostics Clinical Trials

CATEGORIES WON

Collegeville, PA
www.QuestDiagnostics.com/ClinicalTrials

+1 800 209 9816
Terry Burke
Clinical.Trials@QuestDiagnostics.com
Key locations: Valencia, CA; San Juan Capistrano, CA; Teterboro, NJ; Heston, U.K.; Gurgaon, India; Shanghai, China; Singapore

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

MAIN SERVICE AREAS:
Lab

SERVICES & CAPABILITIES: Wide range of laboratory solutions through our unsurpassed global central laboratory and comprehensive biomarker services, diagnostics and esoteric testing, and anatomic pathology services

THERAPEUTIC AREAS: Quest Diagnostics Clinical Trials has expertise in a broad range of therapeutic areas including oncology, CNS, endocrine and metabolic disorders, cardiovascular, infectious diseases, immunology, and inflammatory diseases.

CHRISTOPHER FIKRY, M.D.
vice president, clinical trials

"We are honored to be recognized for the 2015 *Life Science Leader* magazine's Leadership Awards for innovation and reliability. At Quest Diagnostics Clinical Trials we are passionate about developing innovative, groundbreaking laboratory tests to transform information into knowledge and insights – helping our clients to optimize their probability of successfully developing new treatments. Our talented Clinical Trials team of highly experienced professionals, combined with innovative solutions and operational excellence, produce reliable results for our clients."

Quintiles

CATEGORIES WON

Durham, NC
www.quintiles.com

+1 919 998 2000
Robert Thompsen
clinical@quintiles.com
Key locations: United States and United Kingdom

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

MAIN SERVICE AREAS:
Lab, Full Service Clinical

SERVICES & CAPABILITIES: Focused primarily on Phase II-IV clinical trials and associated laboratory and analytical activities

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

PAULA BROWN STAFFORD
president, clinical development

"It is an honor to be recognized in the category of reliability in the 2015 *Life Science Leader* magazine's Leadership Awards. Our biopharmaceutical customers rely on us to not only provide superior delivery today through our award-winning people, processes, and technology, but to also design the transformative clinical development models of the future."

Rho

CATEGORIES WON

Chapel Hill, NC
www.rhoworld.com

+1 919 408 8000
Joan Parks
joan_parks@rhoworld.com
Key locations: United States

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: From Phase I to post-approval, Rho's capabilities encompass regulatory affairs, clinical operations, clinical data management, biostatistics, regulatory and medical writing, quality assurance, and more

THERAPEUTIC AREAS: Rho's strongest therapeutic areas include cardiovascular disease, CNS, gastroenterology, immunology, oncology, and respiratory. Rho is unique among CROs in our balance between commercial and federally sponsored work. Our commercial clients benefit from the experience we've acquired conducting federally sponsored research in areas such as pulmonary hypertension, sickle cell disease, autoimmune disease, asthma, fungal infections, hemophilia, and others.

RUSS HELMS
CEO/CTO

"Innovation, quality, great people, and a team culture are part of our core values. These core values are what have allowed our company to succeed and have resulted in this recognition."

CATEGORIES WON

SanaClis s.r.o.

Bratislava, Slovakia
www.sanaclis.eu

+421917820310
Svitlana Udubkova
info@sanaclis.eu
Key locations: Czech Republic, Estonia, Hungary, Latvia, Lithuania, Russia, Slovakia, Ukraine

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: Regulatory, import/export licenses, clinical monitoring, project management, IMP/CTS local depots, logistics, customs clearance and brokerage, metrology/certification, data management, biostatistics, medical writing, and comparator/rescue medication, and equipment sourcing

THERAPEUTIC AREAS: Cardiology, gastroenterology, gynecology, hematology, metabolic, neurology, oncology, pain, psychiatry, respiratory, rheumatology, and urology

ALEXANDER FETKOVSKY
managing partner

"The award reflects the Sanaclis actual status. Our aim is to work according to the highest industry standards, and to be flexible and reliable so that our clients can benefit from our competitive advantages. Our reliability is based on our business model to provide all services including the logistics by our own staff in our own facilities and under one roof."

CATEGORIES WON

SCYNEXIS, Inc.

Durham, NC
www.scynexis.com/services

+1 919 544 8600
Kerrie Powell
business.development@scynexis.com
Key locations: Durham, NC

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

MAIN SERVICE AREAS:
Preclinical

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

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

YVES RIBEILL
CEO

"At SCYNEXIS we deliver integrated, efficient, and innovative drug discovery and development services that complement our customers' capabilities. Our expert team links great science with regulatory compliance expertise to consistently deliver high-quality GMP material. Our GMP facility has been FDA-inspected with no 483 issues. I'm proud our high standards for safety, quality, and compliance continue to be recognized as drivers of our clients' success as we rapidly solve the toughest drug development problems."

CATEGORIES WON

Seventh Wave Laboratories

Chesterfield, MO
www.7thwavelabs.com

+1 636 519 4885
Joe Flynn
jflynn@7thwavelabs.com
Key locations: Chesterfield, MO; St. Louis, MO

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

MAIN SERVICE AREAS:
Lab, Preclinical

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

JOHN SAGARTZ
president & CEO

"It is an honor to be recognized with a CRO Leadership Award for Innovation. We put the needs of our clients first and share in their passion and sense of urgency to reach their goals. We understand time is money and we remain responsive and flexible, allowing the sponsor to customize each project to meet their needs. We are dedicated to being available to act as an extension of our clients' teams at all times."

CATEGORIES WON

Spaulding Clinical Research, LLC

West Bend, WI
www.spauldingclinical.com

+1 262 334 6020
Tyler Borst
tyler.borst@spauldingclinical.com
Key location: West Bend, WI

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: Phase I - IV drug development services, operates a 165-bed clinical pharmacology unit, core ECG laboratory, and provides biometrics/scientific affairs services

THERAPEUTIC AREAS: Cardiovascular, central nervous system, dermatology, endocrinology/metabolic studies, general medicine, ophthalmology, and women's health

RANDOL SPAULDING
founder & CEO

"Spaulding Clinical is honored to receive recognition from the biopharmaceutical industry for quality and innovation for the second year in a row. Spaulding Clinical's passion for innovation is focused on creating customer-driven solutions that enable lower cost and higher quality data. Innovation and quality run deep at Spaulding Clinical and are a testament to our dedicated professionals and the ingenious solutions they strive for every day."

CATEGORIES WON

Surpass, Inc.

Osceola, WI
www.surpassinc.com

+1 715 294 4371
Amy Stricker-Hume
amy.stricker-hume@surpassinc.com
Key locations: Greater Twin Cities, Silicon Valley, United States

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical

MAIN SERVICE AREAS:
Preclinical

SERVICES & CAPABILITIES: Medical device, pharmaceutical, biotech, combination product preclinical testing in animal models and human cadavers; feasibility, product development, training, and GLP studies; pharmaceutical PK; surgical and interventional expertise

THERAPEUTIC AREAS: Surpass has experience in all therapeutic areas including cardiovascular, orthopedic, dermatological, neurological, urogenital, pulmonary, gastrointestinal, reproductive, and more.

TIMOTHY PELURA, PH.D.
president & CEO

"We are honored to be recognized again this year as a leading preclinical research CRO. As an active member of the medical innovation continuum, Surpass brings more to our client partners, consistently delivering high-quality translational data and innovative solutions that help our clients advance their technologies and therapies to market. On behalf of the Surpass Team, it is a pleasure to accept this award."

CATEGORIES WON

SynteractHCR

Carlsbad, CA
www.synteracthcr.com

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

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: Project management, clinical operations, data management, IWRS, medical/regulatory affairs, medical writing, biostatistics, and staffing

THERAPEUTIC AREAS: Cardiovascular, CNS, endocrinology, infectious disease, oncology, ophthalmology, pediatrics, respiratory, among others

WENDEL BARR
CEO

"As a CRO guiding clinical trials for emerging companies for more than two and a half decades, SynteractHCR is a leader in best practices and intelligent, flexible solutions for leading-edge companies bringing new technologies and drug innovations. We've responded to the increasing complexity of research by educating our clients on processes that will help them become more efficient, reduce costs of drug development, and decrease timelines. We thank *Life Science Leader* for this recognition."

THEOREM
SIMPLIFYING COMPLEX TRIALS™

CATEGORIES WON

Theorem Clinical Research

King of Prussia, PA
www.theoremclinical.com

Sara Davis
Information@TheoremClinical.com
Key locations: Corporate headquarters in King of Prussia, PA; offices in 30+ countries; staff in 40+ countries; access to 22,000 investigator sites

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: Clinical development, clinical analytics, clinical supply, clinical support, strategic regulatory, and strategic outsourcing

THERAPEUTIC AREAS: Cardiovascular, central nervous system, dermatology, endocrinology, general medicine, oncology, orthopedics, radiology/nuclear medicine, respiratory, pediatrics, rare disease, and women's health

JOHN POTTHOFF, PH.D.
president & CEO

"At Theorem, we put tremendous energy into what happens before the trial. We ask questions and we focus on designing and operationalizing trials for the research at hand. During those trials, Theorem stays flexible. As a midsize provider, our processes aren't as rigid as those in place at larger CROs. When a client needs a custom solution, or we need to change our direction based on the research, Theorem can adapt quickly and sensibly."

Vince & Associates
CLINICAL RESEARCH
AN ALTASCIENCES COMPANY

CATEGORIES WON

Vince & Associates Clinical Research

Overland Park, KS
www.vinceandassociates.com

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

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

MAIN SERVICE AREAS:
Full Service Clinical

SERVICES & CAPABILITIES: Early development clinical expertise in a wide range of studies, especially complex clinical pharmacology trials in HNV and special populations

THERAPEUTIC AREAS: Abuse liability, HNV, allergy, cardiovascular, CNS, cognitive testing, substance abuse, dermatology, EEG, elderly, gastrointestinal, hematology, metabolic, obesity, ophthalmology, pain and inflammation, psychiatry, vaccines, and others upon request

DR. BRAD VINCE
CEO & medical director

"I am truly honored by the number of leadership awards Vince & Associates has won. More importantly, this recognition is a true testament to the hard work, experience, and commitment that our dedicated employees put forth each and every day. Our pharma and biotech clients' awareness of our quality and excellence in the CRO industry is what motivates us to continue to set a new standard in early development clinical trials."

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CATEGORIES WON

Worldwide Clinical Trials

King of Prussia, PA
www.wwctrials.com

+1 610 964 2000 or +44 (0) 207 121 61 61
Chris Crucitti
chris.crucitti@wwctrials.com
Key locations: Austin, TX; King of Prussia, PA; Morrisville, NC; United States.; Belgrade, Serbia; London, Nottingham, U.K.; St. Petersburg, Russia

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

MAIN SERVICE AREAS:
Lab, Full Service Clinical

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

THERAPEUTIC AREAS: Cardiovascular disease, chronic inflammatory disorders, CNS, and oncology

PETER BENTON
president & COO

"The entire WCT team is privileged to be named a top provider of quality clinical research solutions for the second year running. Each and every one of us at WCT is committed to supporting our clients - by always being flexible, always finding an innovative approach, and never stopping until the goal is reached. It's honestly the only way we know how to be."

Visit us at BIO booth #3001

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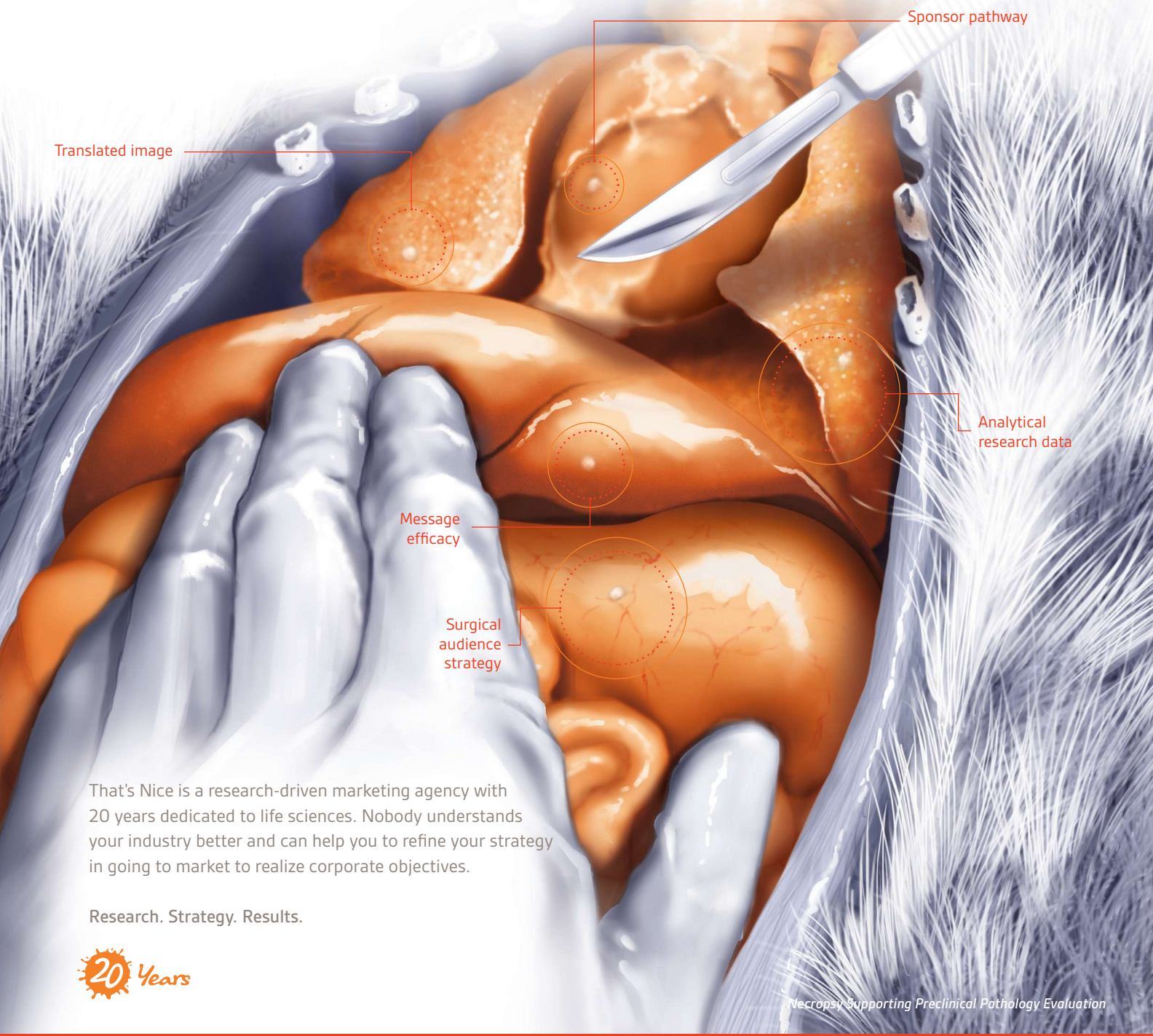

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