Contract Research ORGANIZATIONS

C-Suite executives from some of the industry's leading CROs provide their insights on where the greatest opportunities lie for improving clinical research operations, the greatest challenges involved with the trial process, and best practices to enhance clinical operations.

STEWART BIELER
Chief Administrative Officer
SynteractHCR

Opportunities: Mid-sized CROs have a great opportunity to meet the steadily growing demand for full-service outsourcing services needed by emerging and specialty biopharma companies. Our innovation opportunity comes in aligning expectations and working together to improve the efficiency of clinical trials while continually improving quality. Through collaboration and improved communications as well as by using the most current technological advances available to us, we can help our clients to power innovation and bring tomorrow's treatments to market.

New tools and methodologies, such as risk-based monitoring and adaptive trials, give us the opportunity to streamline data collection, review, analysis, and reporting. We can take advantage of the data available from various sources, such as medical records, centrally collected data including clinical labs or patient-reported outcomes, site monitoring reports, and other trial metadata. Making these data more readily accessible and usable allow sponsors to make better decisions, faster. Data access and integration through better use of technology is an opportunity to help save time and cost and enhance the efficiency of drug development while ensuring quality.

Barriers: Our industry today is challenged by the continuing increase in the complexity of trials, the increase in international locations used, and the changing regulatory landscape. At the same time, this presents opportunity, as increased value is placed on a new breed of clinical development professionals who educate themselves and develop the skills, processes, and tools to meet these challenges and to deliver further innovation and productivity through transformational change. At the end of the day, by doing so, we carry out our mission of delivering a better future and tomorrow's treatments to the patients who need them.

Best Practices: Our industry needs to become a world of global information exchange. By using big data and analytics, sharing information and integrating data through better use of technology, we will make faster discoveries as well as reduce costs and shorten time to market. Ultimately, this world of global information exchange will improve the opportunities for precision medicine.

ALISTAIR MACDONALD
President and Chief Operating Officer
INC Research

Opportunities: We are experiencing so much innovation right now with some new technologies allowing us to dive deeper into engagement with sites and patients. For example, coordinated access to electronic health records provides a great opportunity for us to shorten enrollment times and for studies to include a better understanding of patient history and environment before developing protocols for those spaces.

We know the patients are out there. We know what the trials look like. We know where and who the best sites are. But lining them up in the traditional model of protocol, sites, patients is maybe not the way to do it in the future. Maybe it goes protocol, patients, sites. With the access to additional layers of information, available in real time, there is a lot of opportunity for us to shorten enrollment times by having a better grasp on the patient environment. Matching those elements is a key area of innovation. The other areas of innovation, such as strategic data monitoring, are secondary elements to the access and engagement of sites and patients, although also critically important for running studies efficiently.

Barriers: We have a very structured, well-regulated industry, which should help us to drive innovation. The greatest barriers I see to innovation within clinical research are often among the CROs and pharmaceutical companies themselves. As a group, we need to find a way to share with each other what is working for us and look to share industry best practices that are not really competitive. With technology focusing on pulling all the pieces of clinical research together, big data should help us collaborate to analyze information and findings in order to develop the best approaches to trials and the best treatments for patients. This is a broad industry at work around the globe, which gives us more opportunity to make a difference across various geographies and areas of therapeutic need. All of the elements of the latest technologies should help us pull together more information to make better decisions and drive innovation.

Best Practices: The current best practices that I see making the largest impact are those that are pulling industry groups and talent together to collaborate, bringing standardization and new approaches to the industry, which ultimately benefits the patients. The best way we move forward is through an openness to work with all vendors and contributors, from bench to pharmacy, in the clinical research space. A great example of this has been demonstrated by the great work that TransCelerate has been doing across the industry to help connect the global biopharmaceutical research and development community. We can do more along these lines to help find new therapies and treatments. We are engaging in these efforts through active participation with ACRO and other industry collaborations. It's important that we actively help to shape the future of our industry.

JEANMARIE MARKAM
CEO and Founder
Clinlogix

Opportunities: Timely information is key. Whether it's managing a program or a specific project, access to the requisite data and data analysis reports is the focal point of success. Better leveraging of technology is needed. Life sciences, albeit all of our innovative products and discoveries, lag behind other industries in the optimization of technology to facilitate our day-to-day tasks and decision-making processes. There is a need to facilitate the ability to analyze multiple data sources and compile them into useful reports. Use of predictive forecasting based on these data sources would greatly aid and improve decision-making in the operational arena.

Barriers: Cost and adoption of technology are some of the barriers. More life-sciences companies are smaller and leaner than those of their predecessors. This makes it difficult for those companies to use some of the technologies that the bigger companies have access to. Secondly, due to the ever-increasing burden of regulatory requirements for our industry, there appears to be hesitation to adopt some of these technologies as they are

sometimes viewed as untested and unproven in our industry and may pose a risk.

Best Practices: A few best practices include proper planning and use of the right tools at the right time. It's important to have information that is reliable and timely foremost, and then being able successfully facilitating its exchange within multiple communication pathways among key stakeholders such as monitors, data managers, investigative sites, and patient advocacy groups to ensure key deliverables stay on track and everyone is well-informed closes the loop. Successful operations are a result of good planning, diligence, clear and consistent communications, and timely follow up. Technologies that can optimize and facilitate these tasks such as EDC, SharePoint, and GrantPlan are some examples of tools that can be invaluable to managing operations, especially on a global basis.

DR. SY PRETORIUS
Corporate VP and Chief Scientific Officer
Parexel

Opportunities: We have more data — patient/EHR data, genomic data, real-life/wearable data, etc. — at our disposal than ever before, presenting a significant opportunity for innovation. Part of our current challenge is determining how to best harness all of these data in an innovative way that simplifies the drug development journey, helping to bring new treatments to market faster. There are also various technologies, software, and expertise involved in capturing, analyzing, and processing all of this information. Additionally, I believe that in silico modeling and simulation — informed by the relevant data and supported by the right technology and expertize — holds potential to significantly improve efficiency and decision-making.

Barriers: The culture in our industry is an inherent barrier to disruptive innovation. The stakes in drug development are incredibly high and it is common knowledge that significant capital investment is required to develop a drug. More importantly, we are ultimately dealing with people's lives and health so, understandably the industry does not want to fail or take unnecessary risks. Likewise, development is tightly regulated — and appropriately so — driving an industry culture that tends to shy away from veering off the tried-and-tested beaten path. Many companies are keen on exploring innovative approaches and invest significant time and effort on these; however, more often than not, companies end up favoring proven approaches.

Best Practices: Numerous exciting approaches to enhancing clinical research operations are being explored. These include, but are certainly not limited to, employing more rigorous development frameworks, more rigorous Phase II testing, creative trial designs (e.g. adaptive designs and master protocols), use of biomarkers and patient enrichment strategies, in silico modeling and simulation, data-driven monitoring, data-driven patient, country and site feasibility, ongoing data surveillance and others. Similarly, open innovation, the continued evolution of strategic partnering and vendor use, as well as other innovative commercial and funding models are all enhancing drug development.

NICHOLAS SPITTAL
Senior Executive Director, Global Clinical Services
Chiltern

Opportunities: On a more regular basis we are starting our feasibility process with the patient, rather than the site. Having a real understanding of geographic and ethnic disease prevalence, local standards of care, and population data, and then overlaying that with real provider treatment data, takes the guesswork out of starting a new study. Our traditional manual methods of performing feasibility — Google and PubMed searches, site questionnaires, and trolling investigator databases — can be completely replaced with pinpointing the precise location of specific patients that meet exact inclusion/exclusion criteria for our study protocols. Moreover, by combining provider databases with powerful analytics and visualization tools, this puts the traditional feasibility output on its head.

Barriers: Momentum is the biggest barrier. As an industry we have been too content with the status quo and following the leader. EDC took over a decade before it became standard practice despite the obvious benefits from the start. As an industry, we've been buzzing about risk-based monitoring for half that amount of time already, and while everyone says it's a great idea, it hasn't really caught on. But I think there is real change on this front. We're seeing amazing new devices for data collection. Silicon Valley tech startups are becoming competitors to CROs. Everyone is taking more sophisticated approaches to managing data for clinical and operational decision-making.

Best Practices: We are working on developing a fully integrated delivery solution via site network relationships. The industry has historically treated sites as our service providers — a necessary part of the process, but outside our control or influence. By making sites our partners, there are clear advantages to speed, quality, and ultimately, cost. Jointly going in front of a sponsor with a partner site network — one that can provide the data to support its ability to enroll, having measures in place to ensure its quality, and a willingness and interest to engage in the process — makes us a better and more compelling delivery partner for sponsors. PV