By Taren Grom

Contract Research Organizations

We asked C-suite executives throughout the CRO arena to provide their insights on what the biggest opportunities and barriers for innovation are for improving the drug development process, as well as identify a recent innovation that is improving the process.

STUART ABELSON

President and CEO
Ora Inc.

Opportunities: The short answer is that the greatest opportunity lies in true scientific and operation contribution. Contributing to a sponsor's development program in a non-linear fashion that transcends the value typically placed on outsourcing is the ultimate opportunity. A CRO can provide a greater opportunity for the development partner when it demonstrates an unparalleled, unequivocal ability to enhance the likelihood of the success of its program by mitigating significant risks and enhancing the value of the product. By surrounding the customer with all of the resources necessary, whether regulatory, financial, operational, strategic consulting, or otherwise, the CRO is enabling the ultimate goal, which is getting the product to market.

Barriers: The greatest barriers to innovation are attracting innovative people, creating a regulatory environment that is open to innovation, and finding clients that are willing to consider new ways of doing things.

Clinician-scientist teams with disease-specific experience, tactile operational knowledge, and a clear understanding of the study's drug pharmacology, pharmacokinetics, and toxicology coupled with an understanding of the regulatory pathway are essential in the development of a successful protocol that includes the correct population, time course, and end points. The barrier to entry into the generic CRO space is quite low, and so it's easy to set up shop without the proper knowledge, staff, training, quality systems, and understanding of the true need for innovation in the industry.

The ability to overcome these barriers are what will identify and differentiate high-quality CROs from their generic counterparts.

JIM ESINHART

CEO
Chiltern

Opportunities: With the eClinical revolution of the past decade, clinical research is moving at a much greater speed. There has been nearly universal uptake of electronic data capture and management through EDC, IVRS, ePRO, and other technologies that were only a blip on the radar five, or certainly, 10 years ago. But now we're seeing technological advancement literally explode. For example, this revolution has led Chiltern to successfully implement a wide range of programs using innovative adaptive trial features and risk-based monitoring techniques that are helping our clients work smarter, more efficiently, and yet at the same time, yield even higher levels of quality.

Looking further down the road from outside the industry, the growing wearables market is in its infancy as a consumer novelty today, but imagine how real-time, all-the-time data collection from wearable devices could transform the clinical research industry. These technologies are going to allow us to capture data never before thought possible, potentially eliminating the need for study subjects to ever enter a clinic after their enrollment.

Barriers: Perhaps the greatest barrier is the ever-expanding expectations that eClinical solutions bring. As with any technological advancement, once the bar has been raised, there is a huge appetite — a perception — that we must do more. This creates a healthy tension and our ability to manage that tension becomes key. With implementation of new innovations, particularly something that causes a paradigm shift, there is a huge investment required for training and interoperability. We have to channel that in a positive way to move with the changes, but in a controlled way with respect for our regulatory environment and trial subject safety.

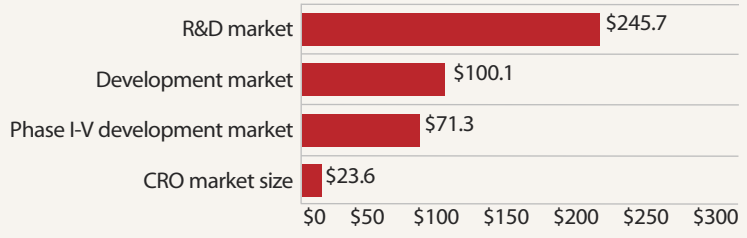
RAYMOND HILL

President
inVentiv Health
Clinical

Opportunities: It is estimated that about $10 billion a year is wasted due to poor investigative site selection. Trial planners simply don't have adequate analytics about research centers and locations where centers operate. Information is often inaccurate and outdated — or simply does not exist. To find the

2014 CRO Analysis

In 2014, the CRO market is expected to comprise 9.6% of the total worldwide R&D market.



Note: Dollars are in billions
Source: ISR Reports

right trial site, across more than 400,000 research centers worldwide, trial planners send out lengthy feasibility questionnaires, often on paper, that are frequently never filled out or returned. inVentiv has applied both advanced technology and process innovation to revamp the entire feasibility process. For instance, through its partnership with ViS, inVentiv brings a sophisticated database and interactive navigation to the clinical research universe, so that trial planners can swiftly match their needs with the disease-specific capabilities of individual research centers worldwide. They can quickly and efficiently evaluate all the relevant analytics, such as local patient population, research activity, infrastructure, personnel, timelines, at the country level as well as down through state, city, postal code, all the way to what is inside the research center facilities.

MIKE JAGIELSKI
CEO
KCR

Opportunities: Innovation is a multifaceted concept, the more so, if discussed in terms of innovation-intensive industries. What directly enters my mind is huge innovative potential for the CRO industry, as well as the clinical operations field, which lies in direct patient engagement processes and technologies. As clinical trials are becoming more and more complex, so are the requirements for patients to be included into trials. In today's world, CROs compete mainly via patient fees to attract sites and subjects. With an increased pressure to reduce research costs, this trend can no longer remain in place. Direct patient engagement might be a path forward to cost-effective subject enrollment.

Although I believe investigators will continue to play a crucial role in clinical research, I assume their impact on recruitment and patient retention is likely to diminish. This shift of responsibilities might ultimately decrease costs and urge CROs and pharma companies to seek more creative and truly innovative ways to directly attract patients to trials, with no straight financial incentive.

Barriers: The current CRO business model, which boils down to CROs charging per hour, seems to hamper innovation. Surely, there might be dozens of CROs that charge unit fees or apply other alternative models, for example, deliverable-based. Nevertheless, the general tendency shows breaking down unit prices to compare them against the hourly model. In my opinion, the model used in the software industry would be more effective. The solution I'm referring to involves license fees for certain key performance indicator or functionality and solution delivery in addition to actual service hours. By employing this kind of business model, CROs might receive considerably more effective ways of project execution, even if it results in fewer service hours sold. The "license" fee might or even should go directly into innovations, such as tools to enhance patient compliance, better remote monitoring concepts, and technology to easily integrate electronic medical records from more diverse sources into trial data sets. These solutions are vital if CROs are to remain competitive with their services.

MARIA LARSON
CEO
ExecuPharm

Opportunities: The greatest innovation that could occur within the CRO industry would be a true "partnership" between a CRO and a client where transparency in every move is expected and realized. When this true partnership is achieved the teams work together as one cohesive unit avoiding unnecessary change orders and delays in timelines. When this model is put in place there are fewer surprises, which increase the budget and fewer crises across both organizations. This also decreases any responsibility gaps across organizations and opens

the lines of communications, in turn creating a more productive working environment and better product in the end, usually in the approved timelines and budgetary guidelines.

Barriers: I believe that the greatest barrier for innovation is ego. The fact that more C-level individuals on both sides are more concerned with being right than being open to innovation is an issue that prevents companies from change. To believe you have all the answers and that your way is the only way to do things could actually halt innovation. As a CRO we are lucky to have the ability to see what is working and what is not for a multitude of companies and able to observe different strategies that are tried within the industry. One of the toughest situations to work through is when a C-level individual insists on a specific strategy that you have seen fail with other organizations time and time again. As a vendor we obviously need to do whatever the client wants, however not putting ego's aside puts everyone on the defense and hence a barrier.

ALISTAIR MACDONALD

Chief Operating Officer
INC Research

Opportunities. I see three areas that are primed for innovation.

First is innovation around technology and the use of data. CROs are getting better and more efficient at gathering and analyzing data for faster decision making. This involves the use of leading indicators rather than lagging indicators. By using metadata, we can identify risks and developing issues as they are happening, rather than waiting for final data. It's an important innovation with a myriad of implications and benefits for the industry.

The second area of innovation is in how partnerships are designed and delivered between CROs and sponsors. Being in a partnership is nothing new, but the approach to the relationship and the commitment that each side makes is where the innovation takes place. Our industry has held itself back in the past in some ways, because each side of these partnerships seemed to have a need for leverage over the other. But as good partnership relationships have matured I think we've learned to have each other's best interests at heart. This leads to great efficiencies as we roll forward with lessons learned, better processes, etc.

Third is a willingness and ability to embrace new directives coming from regulators and to design and deliver trials around these guidances. Risk-based monitoring would fall into this category. It's really up to us to identify where the areas of greatest opportunity and efficiency lie within the guidance and be able to act.

Barriers: We work in a heavily regulated industry and — rightly so — you never want to trade innovation for safety. But the greatest barrier comes from not being willing to risk innovation for fear that regulatory authorities will reject a new approach. Clear guidance from regulators that we can use to build solutions is critical to innovation in the drug development industry.

JOHN POTTHOFF, PH.D.

President and CEO
Theorem Clinical Research

Opportunities: Clinical trials today generate vast quantities of data that must be understood before they can be acted upon. The greatest opportunity for innovation in clinical development of biopharmaceuticals and medical devices lies in advanced software tools and techniques that allow real-time visualization of information in ways that speed understanding. In an era of risk-based monitoring and continual fine-tuning of trial design, connecting data streams with data visualization techniques provides a way for scientists to "see" multiple levels of data as they are generated, revealing new insights that can lead to better choices and decisions.

As more and more data sources become available, this ability to visualize data will lead to an even deeper understanding of patients, products, and processes.

JULIE ROSS

Executive VP, CRO
Advanced Clinical

Opportunities: Business process automation (BPA) is an innovative opportunity to provide a cost-effective and efficient solution to the overall drug development process.

The advantage of BPA is the timely and accurate reporting of data that are pulled from one place, one source of truth, rather than multiple databases with possible data variations. Another benefit of BPA is it allows companies to be system agnostic. Should a company desire to change a related system or database, BPA software will point to the new system or database as a singular place to pull or push data, with the added benefit that data can be aggregated across multiple systems from anywhere in the world. Finally, one of the best features of BPA is the deployment of timelines and costs are a fraction of buying and deploying name brand systems. Processes can be automated one at a time or by function such that ROI can be demonstrated quickly.

KENT THOELKE

Executive VP, Scientific & Medical Affairs
PRA

Opportunities: The escalation of trial complexity and expansion of collected data points continues to increase the burden on both participants and investigators. One opportunity for innovation for CROs is to find ways to streamline this data collection. Key to a CRO's ability to affect change is people supported by a culture of innovation. As the use of EHRs increases at trials sites, the potential to integrate and translate this data directly into data collection tools will become essential to maximize efficiency.

Additionally, the use of mobile and wearable device technologies to collect biometric data directly from patients will decrease the burden on patients and increase the real-time capture of data points. While all of these technologies are doable in the foreseeable future, companies need to them to drive these breakthroughs.

GLYN WILLIAMS

VP, Product Delivery
IDBS

Opportunities: CROs have two main options to achieve success. The first is to be more cost-effective and efficient than large pharma companies or biotechs. The second is to provide a service or niche specialty that larger organizations do not have or are cost prohibitive. There are some options that can be considered in the areas of automation and quality guarantees. There is great opportunity for CROs to innovate by devising new techniques or fostering specialist expertise in specific domains. Customers then pay for leading-edge services at a premium rather than spending money on developing unproven technology. This gives CROs an opportunity to innovate and share the risk across multiple customers.

Barriers: The cost of developing new products and taking them to market is the greatest barrier to innovation. Large companies with the money to innovate tend to focus on economies of scale. Innovations tend to come from smaller companies that cannot compete in terms of scale. These innovations then compete with larger companies or reach a point where bigger players are willing to invest. In these terms the greatest barrier is the perceived risk of innovating. PV

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Clinical Innovations

We asked experts in the clinical field to provide the innovations that they believe are having the biggest impact.

STUART ABELSON
President and CEO
Ora Inc.

Imaging Modality Integration
The integration of imaging modalities into clinical trials such as positron emission tomography (PET) scans of metabolic activity and magnetic resonance imaging (MRI) of bones, joints, and tissues has transformed the way we collect and analyze data and study disease. In the ophthalmic industry in particular, recent imaging developments such as ultra wide-angle fluorescein angiography, adaptive optics scanning laser ophthalmoscopy, and spectral domain optical coherence tomography provide a more precise assessment of ocular structures. This continued innovation in imaging accelerates the pace of drug development and improves patient care for vision-related illnesses. As we embrace these technologies, however, standardization becomes a key component in ensuring that we are collecting, processing, and tracking images in a consistent manner.

JIM ESINHART
CEO
Chiltern

Big Data
Like in all industries, the attention to big data could impact the clinical trial landscape dramatically. This is coming at a time of precipitous pharmaceutical revenue from patent expirations and generic competition, combined with accelerating R&D costs due to the rising price tag for healthcare overall, and the increasing needs for large scale and long term safety monitoring.

Though NHS has recently delayed its release of medical records data, we know this will likely come, possibly with other sources to follow. We need to be stringent in our protection of these data so there is not even a single instance of patient identification, but as a whole, they offer huge value that cannot be ignored. Central repositories will promote a better understanding of diseases and the related effects of pharmaceutical use, help to identify population effects, and reduce the burden of collecting safety and rare events. As a result, clinical trial design may become much more targeted and cost-effective.

MARIA LARSON
CEO
ExecuPharm

Flexibility and Functionality
A notable innovation within the CRO industry is the use of FSPs (flexible/functional service providers), which allows for a more cost-effective solution compared with full-service CROs.

FSPs manage, train, and staff a particular function and this benefits the sponsor by acting more like a true partnership while the sponsor still owns the study. The FSP manages the study, which allows both sides to share in responsibility.

This model, where there is a mutual interest for success from both sides, presents more care and pride is taken within a project. In the end it allows a sponsor company to be more open to new ideas and becomes cost-effective in many ways because the usual expenses are not incurred as they would with a full- service CRO. This allows the FSP to hire more experienced individuals, which equates to speedier timelines being met and fewer turnovers.

ALISTAIR MACDONALD
Chief Operating Officer
INC Research

Metadata Action
The area of greatest recent innovation in our industry is the ability to quickly turn data into actionable information. Innovative systems and technology are producing metadata — that is data about the data itself — that helps us identify trends and issues in nearly real time as collection occurs. This allows us to see developing risks and issues from the program level all the way down to individual sites without waiting until the end of a trial.

KENT THOELKE
Executive VP, Scientific & Medical Affairs
PRA

Virtual Trials
The attempt at a "virtual trial" by Pfizer was quite innovative and represented a true paradigm shift in how clinical trials can be run. While this first attempt at a fully virtual trial did not accrue patients at the desired rate, the attempt and idea was clearly innovative.

True innovation is an iterative process, and I fully expect in this case that a virtual trial, or clinical trials with virtual components, will become much more common in clinical development. There is a need to increase participation in clinical research by the general public, and models such as the virtual trial make participation in trials much more manageable for patients. The lessons learned from this virtual trial will clearly help build a foundation for future innovation in clinical trial execution that takes advantage of technology to fuel efficiency of delivery. And while the methods of a particular trial can help efficiency, innovative environments with forward-looking people will be the engine that drives innovative breakthroughs.

GLYN WILLIAMS
VP, Product Delivery
IDBS

Portable Platforms
I consider the iPad a notable innovation, although being involved in informatics means I might be a little biased. The hardware and software is aesthetically pleasing, which helps acceptance. Its innovation lies in how it has changed the way we use technology and, more specifically, consume and share information. The mobility of these devices means they can be used anywhere, which changes behavior in a fundamental way. Perhaps more importantly, it's providing a platform on which individuals and companies are innovating. It's exciting to see how these subsequent innovations now far outweigh the initial base technology. PV

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