By Taren Grom

CROs: Integrated Outsourcing

Growth Opportunities Ahead

The global R&D outsourcing market by 2018 is expected to be 37.1% of the total pharmaceutical R&D expenditure compared with 25.3% in 2010.

In **GBI Research's** latest report, Contract Research Organizations (CROs) Market to 2018 — Public-Private Partnerships to Strengthen Research Capacities and Advance Clinical Development Programs, analysts say the global R&D outsourcing market is expected to increase by 5% a year until 2018. All companies are looking to cut down the time for launch of drugs along with a reduction in the expenditure on R&D.

CRO industry market revenue was estimated at $21.4 billion in 2010 compared with $19.1 billion in 2009. From 2009 to 2010 the industry grew at the rate of 12%, which is considered to be very healthy in comparison with the other R&D industry growth.

According to clinicaltrials.gov, by November 2011, 43.9% of clinical trials were conducted in the United States; 22.9% in Europe; 11.6% in Asia; and the rest of the clinical trials were carried out in Canada, Mexico, Australia, Middle East, and Africa approximating 21.4% of the total clinical trials.

TechNavio's analysts forecast that the global CRO market will grow at a CAGR of 10.7% from 2011 to 2015. One of the key factors contributing to this market growth is the increase in outsourcing of R&D activities. At the same time, the global CRO market has also been witnessing forward and backward integration by vendors.

WENDEL BARR
CEO
SynteractHCR

Our industry is challenged to make drug development a more efficient process while delivering quality deliverables on time and within budget. As an industry, we have to increase the level of strategic knowledge and insight we provide clients, while ultimately delivering projects of the highest caliber. The common feeling in the industry is that drug development costs continue to rise while deadlines are continually pushed back and deliverables aren't meeting the quality initially promised. The CRO industry as a whole should refine services and deliverables, taking the time to complete due diligence on the front end so our companies can deliver projects as promised.

Clients require programs that can be completed efficiently and this requires a CRO with global offices that can quickly meet their needs and provide flexible, customized services. Clinical trials demand the latest innovations and technologies so data can be managed appropriately. CROs have to have a wide breadth of pharma and therapeutic experience so they can recognize issues up front, saving time on the project over the long haul. Moving to decision points faster is the ultimate goal in clinical drug development and what every CRO needs to remain focused on from the project outset.

We see the ability to leverage technology and provide intelligent clinical development on a global scale as key to driving development efficiencies.

MARK GOLDBERG, M.D.
President and Chief Operating Officer
Parexel International

Asia-Pacific is one of the fastest-growing pharmaceutical markets in the world and has become an integral part of global drug development. Consequently, sponsors need trusted CROs in the region that understand local medical practices and have conducted high-quality trials in the region. These partners must be able to identify how to select appropriate sites that are capable of delivering quality data to support local regulatory filings. At the same time, companies throughout Asia are quickly developing novel compounds, biosimilars, and complex generics. To establish global markets for these products, demand for Western approval is rapidly increasing.

Biopharmaceutical companies of all sizes face increased pressure to bring drugs to market in a cost-effective way, particularly in the post-blockbuster era as targeted treatments become more successful. This, in turn, presents a challenge for CROs since it increases client pressure to outsource clinical trials and other R&D tasks more efficiently.

The current cost of bringing new drugs to market is unsustainable and a revitalized, more effective approach is required. CROs are witnessing a transition away from traditional transactional outsourcing to a new, strategic partnership model. Partnerships have been shown to improve efficiencies, decrease internal oversight, accelerate cycle times, provide access to global patient populations, and limit overhead. In fully established strategic partnerships, speed-to-market can be accelerated by months and cost efficiencies can reach 25% to 30% relative to conventional methods.

ROBERT HOWIE
Chief Marketing Officer
ICON

The biggest opportunity for CROs is to partner with customers to create value for themselves and their stakeholders — regulators, prescribers, payers, and patients — in the value chain. CROs provide a wide range of services across the product lifecycle from compound selection to Phase I-IV clinical trials to market access. Providing these services more effectively, efficiently, at greater velocity, with higher quality, and at lower cost than our customers can do themselves is fundamental to our value proposition, and doing them well is essential. Leading CROs can do more, however, in a healthcare industry whose current model for delivering healthcare is unsustainable. Competition, consolidation, emerging markets and pharma R&D productivity all underscore the need for innovation — technology innovation to accelerate time to results, and business model innovation to develop new capabilities to create value in new ways. Both require trusted partnerships between CROs of sufficient

scale and capability, and pharma players looking for new ways to create that value. Successful partnerships are based on trust, and trust is based on relationships. Predictive analytics through data, and data-driven decision making, will become even more important as part of the strategy to win, as will the need for speed. Doing these things well is critical, but it's equally important to really understand our customers' strategy, helping them execute their strategy by finding new ways to work together and — above all — achieve shared, measurable, value-based outcomes. Creating those outcomes represent a tremendous opportunity for those CROs and their customers both capable and prepared to take advantage of it.

JAMIE MACDONALD
CEO
INC Research

The biggest challenge in the CRO market today is drug development costs that have continued to rise. The industry spends more and more each year on R&D, and yet the number of compounds approved has declined or remained flat. The rising costs are compounded by a slow drug development process and a challenging regulatory environment. These factors represent a real opportunity for CROs to help sponsors overcome challenges by eliminating inefficiencies that drive up R&D costs. The way to do this is through improving the clinical development process and designing more efficient trials by more closely aligning tools, technology and people.

Traditionally, the CRO market has used manual processes, which are labor-intensive; or disparate technologies, which can create inefficiencies. We can remove some of these inefficiencies if technologies and processes are more tightly integrated. This requires innovative solutions that accelerate operations and facilitate transparency, without compromising data quality, allowing sponsors to make informed decisions more quickly. Innovation in the area of technology and study design will provide CROs with the greatest opportunity to play a starring role in saving sponsors money by offering greater efficiencies that ultimately lower drug development costs on a per patient, per study and per compound basis.

JEANMARIE MARKHAM
CEO and Founder
Clinlogix

In the world of CROs, the environment is ever changing. Pharmaceutical, medical device, and biotechnology companies' needs are morphing as the face of the products, people, and processes are trying to keep up with an ever-expanding global market. CROs have the unique challenge of filling in any and all gaps that can arise in a pharma, medical device, or biotech company's ability to get its latest cure from discovery to post-marketing. This is also a CRO's best opportunity.

It is an exciting time to be a CRO; there has never been such a high demand for the services that CROs provide for our clients. We need to be better at what we do, and work to reach more companies that need our support. More and more, companies are outsourcing parts of projects. The company may specialize in part of the process, but realize that it doesn't have the experience or resources for another part. They come to the experts: CROs. There is a great variety in the problems we can solve, providing functional services, only one or many.

Working on only one piece of the puzzle, without working on, or even seeing, the entire picture creates a great challenge. CROs have to mold themselves to fit in with the rest of the process, to make a seamless flow. We are, so often, picking up where others left off, and, so often, where they left off is a mess.

What is a CRO, though, if not a problem solver? Now, more than ever, we have the great opportunity to show what we can do, and how well we can do it to our largest audience.

JOHN POTTHOFF, PH.D.
President and CEO
Theorem Clinical Research

One of the exciting opportunities facing CROs today is personalized medicine. And although the term sounds straightforward, personalized medicine is a complex and multifaceted construct. In the long term, it holds the promise of delivering customized therapeutic agents tailored to an individual's specific proteomic, genetic, or metabolic profile. But in the near term, the most promising aspect of personalized medicine has more to do with using currently available technology to administer today's therapeutics to patients in highly individualized ways. Imagine, for example, a set of implanted drug-eluting beads dispensing a chemotherapeutic dose that is automatically and continuously adjusted — based on real-time tumor cell counts — by a mobile, patient-worn diagnostic/dispensing device. Welcome to today's personalized medicine.

But progress brings challenges. Policymakers are scrambling to craft a framework to ensure that these complex combination studies are carried out safely and successfully. And each clinical trial intended to demonstrate the value of a therapeutic/technologic "joint venture" requires a learned intermediary that can jointly serve the needs of patients and of research teams from both a biopharmaceutical company and a technology/device company. These are the choppy waters CROs must navigate.

How can CROs flourish in this convergence of technology and therapeutics? We believe there are three baseline strategies.

First, CROs must maintain a constant understanding of the regulatory/GCP/ISO environment in which joint trials are conducted.

Second, we need to train clinical research associates to properly manage the clinical and administrative exigencies of joint trials.

And third, CROs need to educate investigators and their staff members so they are prepared to manage not only the normal challenges of conducting clinical trials, but the unique challenges of these complex combination studies.

In the end, those CROs that do their personalized-medicine due diligence will continue to serve the needs of patients and pharmaceutical, biotech, and medical device companies around the world.

LEO SHERIDAN
CEO
Advanced Clinical

CROs have an excellent opportunity to lead the effort in digitizing clinical trials. Through automating key business processes in the clinical-trial process, efficiencies are created and save pharma companies time and money. Since clinical trials are not meeting timelines across the industry, adopting and embracing new approaches to clinical-trial management is critical in improving this result. Additional value is also created in areas such as patient retention and compliance. The challenge to adopting this modernization often sits within the pharma companies themselves. While pharma companies are undoubtedly interested in creating efficiencies, they are often not set up to embrace these types of innovations and would likely need to implement structural changes. CROs that can collaborate with pharma to integrate this approach will lead the industry in changing the way trials are managed.

One of the challenges CROs continue to face is providing first-class service to clients with optimal results while maintaining low overhead costs. To offer competitive pricing, CROs need to balance the demand for qualified, experienced clinical research professionals with keeping low numbers of staff who are not at optimal billing capacity. Some CROs overcome such a challenge by supplementing resources needed through in-house staffing divisions and accessing their extensive talent pool. This allows CROs to pull in professionals who are already evaluated when the clients' needs or programs change, or to quickly ramp up efforts to meet study timelines. This works exceptionally well when CROs spend significant time developing relationships with qualified professionals working in every function within the clinical research field. PV