
# Q2 2013: Inside this Issue

Welcome to the most recent issue of Lincoln International's Healthcare DealReader, a newsletter focused on market dynamics, merger and acquisition trends and events of interest to owners and managers of healthcare businesses globally.

At Lincoln International, we specialize in providing unparalleled merger and acquisition advisory services to corporations, financial sponsors and privately-held businesses worldwide. Our knowledge of the healthcare sector, global footprint and commitment to understanding our clients' unique business models has allowed us to successfully pair our clients with partners who are ideally suited to meet long-term growth objectives.

In this issue, we are pleased to share with you an interview with Dr. Caroline Popper and Dr. John Mills assessing the contract research organization (CRO) industry.

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## CROs: Growth, Technology, Globalization and Consolidation

CROs serve an integral role in the drug development process, offering a broad array of services to pharmaceutical, biotechnology and medical device companies. The CRO sector, like many sectors in the healthcare industry, is growing and experiencing considerable changes as it adapts to technological innovation, ongoing globalization and consolidation.

Historically, CROs served as tactical outsourcing providers offering pharmaceutical companies additional clinical trial and lab capacity on an as-needed basis. Today, the CRO industry has grown into a $25 billion market worldwide. CROs have expanded their breadth of services to resemble, in many cases, the large-scale pharmaceutical companies they serve, which has alleviated pharmaceutical companies from the burden of maintaining full-scale drug development capabilities in-house. CROs are now valued as strategic partners by their clients, which is reflected in the highly coveted, long-term strategic alliances being formed in the industry. This is due, in large part, to the intense pressure pharmaceutical companies now face to accelerate the discovery, development and commercialization of new drug candidates to replace substantial revenues lost each year to generic competition as branded drugs lose patent protection.

Across the CRO industry landscape, a small number of large competitors has emerged. To better compete with this top-tier, many of the mid-tier players are bulking up by adding capabilities through targeted acquisitions. Companies with global capabilities and advanced technology tools to better manage patient recruitment, trials and data are all of interest. There are many independent specialty and full-service CROs globally that are and will be attractive to strategic and financial acquirers alike. As a result, CRO industry consolidation is expected to remain active in the middle market. Given such broad interest in the sector, Lincoln International's Healthcare team has asked Dr. Caroline Popper and Dr. John Mills of Popper and Company to share their thoughts on current trends impacting the CRO industry.

## An Interview on the CRO Industry with Dr. Caroline Popper and Dr. John Mills

### As large CROs continue to get larger, where do you see growth opportunities?

*Mills*: Big CROs have become large enough to enable pharma sponsors to deal with one or a limited number of outsourcing partners, rather than multiple sources. However, this poses issues for middle size companies that do not have the same scale. I think we will continue to see a great deal of activity from mid-size companies as they seek to build up these overarching capabilities. Though they may not get into the Top 15 pharma, there is still a very big marketplace in the mid 20-30 pharma companies, which are also going to require more comprehensive services. The other observation is that the big players are becoming cumbersome; it's almost inevitable that when you work with a large company there are delays. The mid-size companies have the ability to be nimble.

*Popper*: There is opportunity for mid-tier players to grow fast by offering a different type of service than the more routine offerings one sees at the big CROs – and offer it more quickly and with more flexibility. However, it's also going to be necessary for the mid-tier CROs to globalize.

### What services should mid-tier CROs be focused on to be more competitive?

*Mills*: I think a mid-tier CRO should consider building relationships with some form of lab, particularly one with a specialty or a niche, rather than having to use one of the bigger labs. Companion diagnostics is an area that large pharma is certainly interested in developing further. Monitoring therapy will likely be a key area for differentiation.

*Popper*: Across the board (in diagnostics, devices and therapeutics) there is an increased interest in post-market surveillance (PMS) trials as a "price" for accelerated approvals. As pharma companies push for earlier approvals, this will decrease the need for large-scale clinical trials on the one hand and increase the need for better PMS technologies and systems on the other.

*Mills*: I would add that whether you are big or small in this business, developing multinational relationships with site management organizations will be very important as patients become the scarce resource.

### How is technology impacting drug development?

*Mills*: We have seen that patient enrollment is very important in Phase III. Studies that enroll quickly will make money and deliver on time. There are some technologies that allow you to acquire good data quickly when monitoring studies, which reduces time and minimizes clean up at the end of the study. Additionally, there has been a real move towards adaptive clinical trials, where the trials are modified as you go along, in view of the data coming out of the trial.

*Popper*: While the mid-tier CROs are trying to replicate the big CROs, they should perhaps be trying to leap frog them instead. One way to do this is through technologies and focus rather

than just replicating what has been done and bought already. There is an increasing interest in CROs that integrate a variety of outsourced pharma services and digital technologies, thereby making clinical trials more efficient. Actually, the whole point of health system efficiency is equally as relevant in drug development as it is in healthcare delivery. Companies with advanced technology tools to better manage recruitment, trials, data and information generation, are all of interest, as is the use of the cloud, not only for data storage but also for the massive computational capacity it enables that is critical in the development process. Put another way: the outsourced pharma services sector is an important arena for opportunities leveraging the convergence of digital technologies and healthcare. There are numerous opportunities in this arena from capturing more and better data at the pre-clinical phase, to driving better utilization of trial participants in the clinical phases.

## Can you expand on the theme of converging digital technologies and healthcare?

*Popper*: Fundamentally, it is all about efficiency. One of the real values of 'Big Data' in healthcare is to expedite and make drug development more efficient by using all these parameters to make a better selection about patient population. The companies that are developing these technologies are highly relevant.

*Mills*: In the case of drug development, one of the benefits is that you can now centralize data globally and have rapid cleanup to quickly arrive at a homogenous data set. In the future, we are going to have to be able to handle very large quantities of data, including large amounts of genomic data, to identify populations of patients. I do not see how we are going to do trials in the future without significant capabilities to merge data streams and handle the analysis of very large quantities of data.

## What do you see as the drivers and challenges of globalization in the CRO industry?

*Mills*: Globalization has a number of components. The original drive, which still persists today, was to look for patient populations. If you are going to launch a drug around the world, then the ideal is to do a synchronized study globally. It has not always been done, though it is easier to do now. Today, CROs are well organized and very good at identifying patients that can be placed into trials. The second thing about globalization is that economies in emerging markets are growing and developing a middle class, which has increased dramatically in the last 15 years. Given the wealth of these countries, one does not only need a presence but also must address the needs of these markets. For example, there are certain diseases that you see in developing countries, such as malaria, which have not been given much attention by the pharma industry.

*Popper*: Another challenge for globalization is finding quality CROs overseas; this is where Lincoln can be very helpful. CROs should be looking to add capabilities in areas like recruitment or analytical work onto a platform that already has a global footprint.

## How will these changes in the CRO landscape impact M&A?

*Popper*: Accessing these new entrants and high-growth companies early is the key to acquiring the best talent and capabilities. The CRO industry is a global one, and there are still a lot of independent specialty CROs worldwide. Thus, you will continue to see consolidation among niche and mid-size competitors as companies and investors look to acquire broader sets of capabilities and a more global platform. We also expect to see new entrants in the space, like big information companies, making a big play through a series of acquisitions and consolidations.

## Do you see an opportunity for mid-tier players to consolidate?

*Mills*: It's almost inevitable that something like this is bound to happen. Perhaps by taking two companies and putting them on the market together. Otherwise, they run the risk of getting squeezed. Go global or go niche has to be the mantra.

## Caroline Popper, M.D., M.P.H.

Caroline Popper currently serves as Co-Founder and President of Popper and Company, a strategy firm focused on efficiencies in diagnostics, life science tools, health services and digital health. Dr. Popper has more than 25 years of hands-on biotech/life sciences operating experience. During a 10-year career at Becton Dickinson (NYSE: BDX), Dr. Popper's global responsibilities included clinical affairs, marketing, strategy and business development. From 2000 to 2002, she was the Chief Business Officer for MDS Proteomics. Today, Dr. Popper and her colleagues at Popper and Company leverage their extensive knowledge of the trends and forces shaping the life sciences industry and its participants. Dr. Popper received her medical degree from the University of the Witwatersrand (South Africa) and her M.P.H. (Health Policy and Economics) from Johns Hopkins University (Baltimore). She is an internist and pathologist. Dr. Popper is currently a board member of NanoMR, RPS biosensors, Rarecyte, LBT Innovations (Australia) and Pronota nv.

## F. John Mills, M.D., Ph.D.

John Mills is currently a strategic advisor for Popper and Company as well as the Chairman of the Board of BioStorage Technologies, a company he co-founded in 2004. Prior to founding BioStorage Technologies, Dr. Mills served for three years as corporate senior vice president and president of clinical support services for Covance, Inc. (NYSE: CVD). While there, Dr. Mills was responsible for a $300 million-per-year clinical services division that employed more than 2,000 staff members globally. For six years prior, Dr. Mills was based in the United Kingdom as corporate vice president for Covance's European clinical division. Prior to his career with Covance, Dr. Mills held senior positions in Asia and Europe with Janssen Pharmaceutica, a division of Johnson & Johnson, Inc. Dr. Mills received his M.D. from Cambridge University and his Ph.D. in endocrinology from Surrey University in the United Kingdom.

## Recent Lincoln International Healthcare Sector Transactions


## About Lincoln International

Lincoln International specializes in merger and acquisition advisory services, debt advisory services, private capital raising and restructuring advice on mid-market transactions. Lincoln International also provides fairness opinions, valuations and pension advisory services on a wide range of transaction sizes. With fourteen offices in the Americas, Asia and Europe, Lincoln International has strong local knowledge and contacts in key global economies. The firm provides clients with senior-level attention, in-depth industry expertise and integrated resources. By being focused and independent, Lincoln International serves its clients without conflicts of interest. More information about Lincoln International can be obtained at www.lincolninternational.com.

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| **Medical Devices and Products** | Orthopedics; Custom Mobility, O&P and HME; Institutional Equipment and Products; Dental Products; Surgical Tools; Wound Care; Respiratory and Sleep; Minimally Invasive; Components and Supplies |
| **Diagnostics & Research Tools** | Diagnostic Systems; Diagnostic Equipment; Assays; Research Equipment; Research Instruments; Laboratory Services; Research Services; Diagnostic Supplies; Consumables |
| **Outsourcing Services** | Analytical Lab; Contract Research; Process Development and Design; Contract Manufacturing; Marketing Services; Contract Device Services; Clinical Site Management; Regulatory and Reimbursement |
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