Insider Insights:  
Chiltern International

CWWeekly’s semi-monthly company profile feature, Insider Insights, interviews executives of companies and organizations in the clinical trials space. Writer Ronald Rosenberg sat down with Jim Esinhart, CEO of Chiltern International.

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Strategic alliances between sponsors and CROs continue to show they saved money, but only in the long run, only after hefty initial costs and the relationship matures to a point at which the CRO learns and refines the processes that can bring the sponsor efficiencies. How have strategic alliances affected Chiltern’s U.S. growth, and where do you see the outsourcing trends for CROs going in the next three to five years?

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Chiltern has been successful at building strategic partnerships and alliances with mid-tier pharma and biotech companies, and also with large pharma in niche areas, such as study startup via Chiltern Activate, pharmacovigilance and biometrics. These relationships are international, including the U.S., and are collaborative with shared goals and investments and focused on streamlined and more effective delivery, which equates to meaningful cost savings.

In terms of shared goals, clients want to see lower costs and improved delivery and efficiency. In return, CROs want to see a steady and rising volume of work at a reasonable margin once start-up costs have been factored in. There has been a great deal of speculation around CROs attracting strategic deals at or below cost, and we will see over time whether operating margins are maintained to reflect increased revenues. However, we believe most strategic deals have been negotiated on the basis of shared and mutual benefit and, at Chiltern, this is how we are approaching ongoing strategic relationships.

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As a global company, Chiltern has recently expanded to Israel, Taiwan, and emerging markets to conduct trials as the ability to recruit patients in the U.S. has decreased. Given that there is a significant pool of patients in the U.S. not participating in clinical trials, what do you believe is needed to improve recruitment and retention of American patients/volunteers?

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Approximately one third of Chiltern’s business is in North America, and it is currently our fastest growing region. This rising volume of business has been due to the increased size and volume of clinical trials we are conducting in the U.S. market and the growth of functional service deals and structured strategic arrangements. We are growing in the U.S. even though the number of patients recruited to trials in the U.S. has been flat or falling.

Chiltern has joined the trend to globalize, which has seen an accelerated shift to clinical trial globalization and off-shoring over the past 10 years. While it is hard to imagine this trend reversing, especially with the rise of emerging economies, there are compelling reasons to focus patient recruitment in established markets such as the U.S. This is partly due to the fact that established markets are rapidly evolving economically, demographically and structurally. Sponsors are finding they can further maximize their market potential if they demonstrate the worth of their products with real-world evidence of lower mortality and morbidity rates and savings in total healthcare costs.

Headquarters: Slough, U.K.  
Year founded: 1982 in the U.K.; U.S. operations launched in 2002  
Description: A global CRO managing phase I-IV clinical trials and contract staffing solutions in more than 40 countries. Services include early phase, global clinical development, late phase, biometrics, medical and regulatory affairs and resourcing solutions. It provides fully comprehensive data management, EDC Study Build, EDC training/consultancy, statistical and medical writing services.

Officers:  
Jim Esinhart, CEO  
Aize Smink, Chief Operating Officer  
Linda Christmas, Chief Resourcing Officer  
Owen Lewis, Executive VP, Global Legal Affairs & General Counsel

Offices:  
Chicago, Wilmington, N.C., Bristol, Tenn., Argentina, Brazil, India, Belgium, Czech Republic, France, Germany, Hungary, Italy, the Netherlands, Poland, Portugal, Russia, Spain, Switzerland and Ukraine

Number of trials since 2000: 681 worldwide  
Clients: large, medium and small pharmaceutical, biotechnology and medical device companies

Employees: 1,400 worldwide  
Web site: www.chiltern.com

We believe the U.S. clinical trials market has tremendous potential for growth and this will, of course, depend on many macro-economic factors and our ability to recruit patients cost-effectively relative to the rest of the world. It is often quoted that only 2% of potential U.S. investigative sites are utilized for clinical trials. The results of a May 2008 survey conducted by The Center for Information and Study on Clinical Research Participation (CIS-CRP) indicated that 94% of Americans have never been informed by their doctors about...
medical research studies for which they might be suitable as potential participants. So there is no doubt that the U.S. market for clinical trials can grow and should grow.

Q Complex and unrealistic protocols not only cause trial delay, they also discourage patients from participating and raise concerns from IRBs. What reforms would you like to see to mitigate this problem?

A The answer begins with communications, notably better and more timely communications. Reforms such as Fast Track designation and Accelerated Approval have greatly improved the approval times for serious and life-threatening diseases for which there is an unmet medical need. Along with these reforms, sponsors often have frequent meetings and access to regulators to discuss the development plans to ensure the collection of appropriate data for those programs.

We also advocate additional investments to understand the "recruitability" of complex protocols with assessment of real patient data. As an example, Chiltern was recently engaged as part of a development team of scientists, physicians and clinicians to assist a sponsor to develop a novel study protocol. Several criteria including allowable concomitant medications, frequency and schedule of protocol procedures and inclusionary diagnostic results were carefully assessed individually as having low impact on recruitability.

Taken together, we believed this would make trial recruitment unfeasible. So we contracted with three investigative sites to conduct a review of their patient databases for eight key protocol elements and found approximately 3% of patients with the target disease may qualify for the study. This was an eye-opening event for all involved, and this small up-front investment saved thousands, if not millions, of dollars for the sponsor. It also allowed us to retool the study design up front instead of mid-study.

Q Given Chiltern's strength in phase IV studies, what is your view of Comparative Effectiveness Research (CER), which is being pushed by regulators, the public and health insurers for new medications to determine "overall product value" and the increased performance of marketed drug devices and other therapies. This would show comparative effectiveness as well as identify gaps in the existing data.

CROs are well-positioned through their scientific and operational expertise to contribute to the efficient design and management of observational research and the evaluation of stakeholder input. We as CROs view ourselves as partners in CER efforts and a primary player in the gathering of high-quality evidence in the real world.

Q While some CRO leaders acknowledge the clinical trials industry is flourishing overseas, particularly in Eastern Europe and Asia, what do you tell aspiring CRAs in the U.S. who will need to develop new skills and accept a changing role that may be somewhat different than today's CRA careers?

A This is not a unique U.S. concept. This is a great opportunity for current CRAs who have been in the industry and have already become accustomed to its constant change; evolution of the CRA role is not new. In the recent past, we have seen CTMS, EDC and ePRO technologies shift responsibilities with an increased ability to monitor data remotely. This will continue with the rise of EMRs as e-source systems and the growing use of mobile technologies.

For tomorrow's CRAs, this requires an understanding of and comfort level with technology. The tradeoff may come over time, with reduced travel and a growing focus on building long-term relationships. We also are seeing more utilization of dedicated in-house CRAs and site relationship management that focuses entirely on monitoring data remotely and maintaining site rapport. So, the career path for CRAs and others is most assuredly continuing to morph, yet for those with an appetite for changing dynamics we can expect huge opportunities for near- and long-term growth.