Interview with Barry Silverstein, Country Manager UK and Executive Director of Commercial Operations, Chiltern UK

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Given the global trend of clinical research increasingly being outsourced to emerging markets, such as Asia and Latin America, where does this leave historical hubs of clinical research such as the UK?

I am confident that the UK will remain a key region for research and innovation for the global pharmaceutical industry. Mature markets such as the UK have an established infrastructure and talent pool that encourages quality and efficiency. Emerging markets have much to offer in the nature of untreated patient groups, and the establishment of new facilities and research centers. Emerging markets also offer opportunities for the professional development of new and less-experienced staff, but as these elements have not matured, many operational challenges will remain that are not available yet compared to the UK market. We have witnessed the mix of services have shifted in the UK with fewer patients being recruited here as part of global trials but there has been a notable increase in the service geared to provide leaderships to clients such as increased numbers of Project Managers, Data Managers and Medical Monitors. The UK has a clear advantage in the level of expertise and experience of the market, as well as companies that possess established processes that are necessary for the success of clinical research.

Does this mean that Chiltern will continue to focus on mature markets as part of its strategic focus?

Chiltern was established in the UK, with a predominant focus on the European and North American markets where our brand is very well known and respected. This being said, Chiltern continues to grow and recognizes the need to establish a larger global footprint through a mix of acquisitions and organic growth in regions outside of Europe and North America. For this reason we have already embarked on growth plans in emerging markets, such as South America and Asia, and have developed a strategy to expand into those and other key locations.

As a global CRO, what advantages does the UK offer clinical research companies as a home base?

The advantages for us at Chiltern are that we have a very established brand within the UK and we have good relations with North American and European clients. The high level of quality staff is also exceptional in the UK, specifically because it is a mature market for the pharmaceutical industry and one that has historically been a hub of excellence for research. Whenever we are looking to attract experienced staff to the company, we know that we can rely on our location and our established brand in the UK to attract those kinds of people.

While the UK has in the past been a preferred location to conduct clinical trials, the cost of trials and times for approval have more recently been noted as disadvantages of the UK's clinical research environment. How has this impacted the local clinical research environment?

As regards the slower approval times, I don't believe it is fair to generalize that overall approvals have become slower. In terms of regulatory approval, I would even say that the MHRA has done a fantastic job in maintaining high quality review requirements while at the same time meeting the deadlines they establish for themselves. Where the UK does struggle is with the additional approval requirements from other local stakeholders, such as R&D and investigator networks that have been established to improve the research environment in the UK but ultimately add an extra layer of approval before start-up of trials. Despite this sort of fragmentation, I do see the move towards greater coordination with initiatives like the parallel process for ethics and regulatory approvals. Overall, the cost of clinical research in the UK is comparable to the US and Western European countries as a trading block, and needs to be differentiated from the emerging markets. Because of the economic pressures that pharmaceutical companies have been experiencing over the last few years, they have resorted to find greater cost efficiencies throughout their entire value chain. Whilst there may strong cost incentive to conduct some elements of clinical research in emerging markets, a large range of core services are performed very efficiently and competitively in the UK. The advantages of the UK lie in the excellence of the research that is conducted here and the level of professionalism that is expected from British scientists.

Do you foresee that the UK will then become a specialist market for early phase clinical trials in which smaller patient groups are required while the later phases are outsourced to emerging markets because of the greater availability of patients?

I see the overall UK market growing through the types of relationships that CROs will establish with pharmaceutical companies. Essentially, these relationships will become a great deal closer and there will be a greater exchange of systems and processes across companies. The global economic downturn had a deep impact in the development of new products by pharma companies and biotechs which then sharply decreased the demand for early phase trials. At that point many CROs found themselves with an excess capacity for early phase trials and only those companies that specialized in that segment have continued to develop their businesses.

What do you consider to be the UK government's most successful initiatives to attract further clinical research to the country?

At the level of the MHRA, I feel that the UK government is taking the necessary steps to foster an appealing clinical research environment. In particular, they have been very supportive of a pan-European initiative called the Voluntary Harmonization Procedures (VHP), where European countries integrate regulatory approvals across all participating agencies. The MHRA is still perceived as one of the flag bearers of European regulation and are at the front-end of bringing back more clinical trials to the region.

What services does Chiltern offer its clients in the UK to expedite the clinical trial process and ultimately minimize costs?

We have developed an initiative called Chiltern Safe that aims to manage the large amount of documentation that is typically generated throughout the lifecycle of a clinical trial. We recognized that many of our clients do not have seamless and uniform Trial Master Files across all of their clinical research providers. Having different formats creates the need to then compile and coordinate all the data so that it can be presented clearly to the regulatory authorities. Chiltern Safe provides a streamlined and safe way of controlling the documentation process of a trial so that submissions to regulatory authorities can be made quicker.

Another service we have developed in response to the increasing use of electronic data capturing (EDC) is something we call Collaborative Technologies, which allows for the electronic management of ongoing clinical trials. This allows our clients to access live information and documentation on their trials.. This is a proprietary product developed by Chiltern, but I predict that similar platforms will become standard practice within the sector.

Which of Chiltern’s services are driving the company’s growth worldwide?

Aside from providing clinical research services, Chiltern also has a large staff outsourcing business that is growing considerably. Six years ago, the company’s senior management observed that the market for pharma staff outsourcing was very strong in the UK, Europe, and North America and therefore made it one of our strategic priorities. At the moment, 25% of our global business is the outsourcing of staff. This business also allows us to carefully manage any fluctuations of our staff resource needs depending on the amount of clinical research activity at any given time. Essentially, we are responsible for managing the individual that is placed at our client’s site and we have managed to build a strong reputation by providing this kind of service. Chiltern is now looking to expand this kind of business in the US and in emerging markets. We are also looking at expanding our biometrics, biostatistics, project management and regulatory groups in the UK because of the quality of staff here. Chiltern recognizes the value of human resources in the UK and will not relinquish such experience and expertise despite global trends of CROs moving to emerging markets.

You’ve held a number of positions in the industry both in pharmaceutical companies and major global CROs. What was it about Chiltern that attracted you to work here?

It was 100% the culture of Chiltern that attracted me here. This is a much more diversely managed company than what you would find at other global CROs. Chiltern’s global management team is based out of the US, the UK and Europe and yet I feel very close to the strategy and direction that this company takes. The UK is the largest affiliate of the company, and I wanted to be based here, so it was a great opportunity for me to lead one of Chiltern’s largest offices.

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