BioSpectrum the business of Bio & Health Sciences

"India offers favorable conditions for clinical research"

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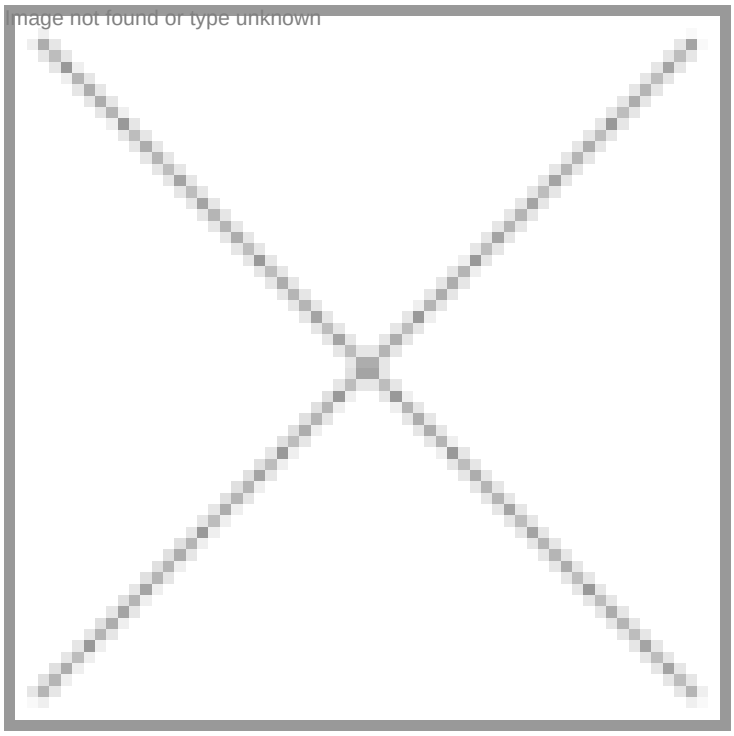
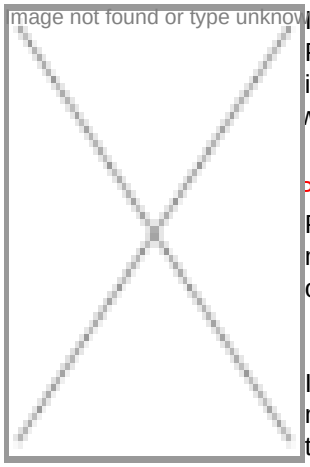


—Simon Britton, VP, Clinical Development, Asia Pacific, PPD.

Significant work migration from India to China is expected in the coming days



In India, PPD has offices at Bangalore, Mumbai and New Delhi. Recently, Simon Britton, Vice President (Clinical Development-Asia Pacific), PPD, on a visit to India and China, in an exclusive interaction with BioSpectrum, spoke about the services PPD provides in India, Indo-China market wth of the industry.

PD provide in India and how is it unique?

PPD mainly offers monitoring and project management services in India. We are interested in making India a major part of our operations, but we primarily intend to provide global services. We operate in multiple countries; and have a significant presence in Asia, Eastern Europe and North

In therapeutics, we focus on many areas and the major segment is oncology. The PPD staff number 11,000. Given the conducive environment and the predictable regulation, there is a lot in terms of service that PPD can provide. Although we are yet to start lab services in India, our clinical research associates (CRAs) are well trained and capable of high quality of work.

Q Have there been any issues with availability of volunteers?

The infrastructure, manpower, clinical trial accessibility in India are conducive for our business. India has a sizeable

population of 1.2 billion. There are really no manpower issues.

Q How do you compare markets in India and China?

At the moment, there is a significant difference between markets in India and China. India has better quality and English-speaking skills. There is a clear maturity of research and manpower skills. The regulatory environment is predictably good; and the Drug Controller General of India (DCGI) has made considerable efforts to improve it. India is much more in line with countries like the UK and US. India has a significantly better regulatory aspect; and offers a competitive edge over many other countries. India is seen as a quality-provider; and Indian operations are a gateway to the rest of the world.

In comparison, China is trying to improve standards on many fronts. One of the problem areas in China has been the time (period) taken for trials. The phase III and IV take a lot of time (close to 15 months). However, China is striving to decrease the time duration; and this can lead to migration of significant work from India to China, in coming days. Besides that, China and Taiwan are investing heavily in the overall biotechnology market.

Q What challenges do you face in India?

There has been a lot of skepticism about working in India. Despite that, things have started to change now. Personally, I ama huge advocate of India, and the huge market potential it offers. However, there are concerns about Intellectual property (IP) with regard to India. Also, I think due to lack of individual medical records, there have been certain reservations about conducting trials on Indian population. The challenges are there, but PPD as a company, is always ready to advise and provide help in this direction.

India has become more predictable in the past couple of years. Clinical trials must see improvement by reducing time, and making it more predictable. PPD conducted audit along with the DCGI; and the audits should be a continuous process. India needs to be more clear on the biosimilar front. Currently, a sizeable number of trials are ongoing, and a 60 percent increase is projected for the future. No doubt, DCGI has played a great role in streamlining things in India. Now, it can add many more resources to make things more predictable and better. We are looking forward to sooner availability of physicians and the permission to conduct trials.

Q What kind of growth has the Indian market witnessed so far?

India has seen a lot of growth, although a slowdown in the clinical research market is witnessed in recent times. All this happened at a time when politicians were pushing biomarkers for individual patients. The last two years have provided a good base.

The recent BioIndia at Hyderabad saw deliberations on IP management, protection and increase in the degree ofconfidence. If India grows at the same rate, we can expect a similar growth in the clinical research market. With regard to PPD, we are looking for a slow but substantial growth, if not doubling our revenues in coming times.

Q What are your views on India's talent pool availability? Did you encounter any issues during recruitment?

There is a huge pool of talent available in India. It is easy for us to find personnel with the right attitude, expression and integrity. Clinical research is new to India, as it started moderately in the last 10 years. There are only a few people with experience, but now with time, it is easier to find top talent.

So far, we have not witnessed any recruitment-related issues here at PPD. Also a majority of our workforce is into project management and clinical research associates (CRAs). We do not provide back office support or downstream process here, as most of that happens outside India, although we have some HR and finance sections here. At the same time, we may look into expanding; and increasing our workforce in this area too.

Q What is the status of the current trials being conducted at PPD?

There are a significant number of studies that have been going on. Among those, the number of oncology andcardiovascular studies is larger. Currently, about 70-80 studies are going on. We have our sites at strategic locations, and they provide us with an overall ability for successful trials. For local clients, we also offer to conduct phase I R&D of novel drugs.

Q Do you have any partnerships in India? What are your future plans for the Indian market?

We are working closely with some site contractors. As of now, we do not have any partners in India, but are not averse to mergers and acquisitions (M&A) in the near future.

A unique point that lies with us is that we are a zero-liability company, and we have a liquid balance of $6 billion. That gives us a sense of freedom; that we can add supplementary services, and always be ready to talk to anybody for broadening our

horizons.

In 2011, we plan to build on what we already have. We would be looking forward to adding more workforce and capacity, including, broadening geographical region. Apart from cities, we plan to locate staff in other sites. Another area of focus would be providing additional facilities — the sites located in the North East will have permanent trainingcourses for investigators and faculty members.

Rahul Koul in New Delhi