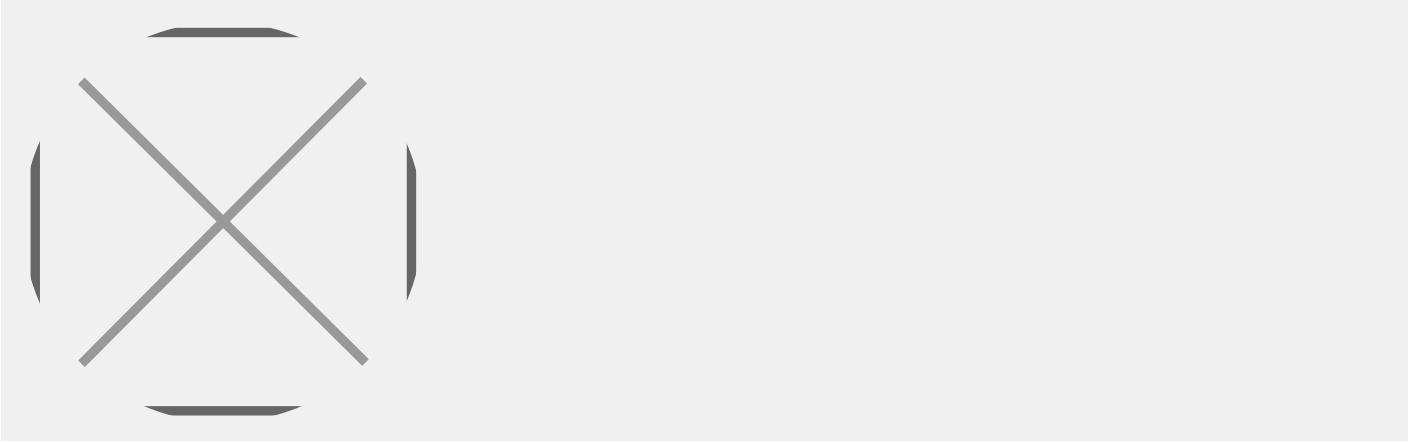
Interview with Baljit Samra, Country Manager, Parexel India



27.07.2012

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PAREXEL has had a long-term commitment to India. Could you give us a brief overview of your activities in the country?

PAREXEL offers clinical development services throughout India. In 2004, PAREXEL entered into a joint alliance with Synchron then expanded our presence in India. In 2007, PAREXEL opened an office in Hyderabad to offer its clients a wide range of clinical research and data management services while expanding on its existing services in Bangalore, and deepening its long-term commitment in India. We have a team in India that supports our regional and worldwide operations. Our services in India include data management, clinical monitoring, medical writing, and pharmacovigilance, as well as regulatory affairs. We also have medical imaging operations.

India represents 0,5bn of an overall 20bnUSD CRO industry. How do you see this evolving, and how important will India become for PAREXEL and its clients?

India and the Asia Pacific region continue to be important geographies for biopharmaceutical development. With a strong presence in India and expansive global footprint PAREXEL is supporting clients to bring their products to market. India continues to be an important location, to meet client demand for our services. Through a growing presence in India, we look forward to continuing to meet a global and local demand by providing a broad range of expertise and capabilities, including eClinical solutions to accelerate development.

India is still a relatively new destination in the global clinical trials map. Today, how would you assess the maturity of India, and its potential to become a clinical trial hub?

India is evolving as one of the world's preferred destinations for clinical trials. India is attractive for its international access, sophisticated healthcare system, and focus on higher education, including being home to leading medical institutes. We recognize that India has an excellent clinical research environment, and recent changes are making India an increasingly attractive market to our global client base. India is aligned with ICH-GCP guidelines, and there is a strong and growing network of experience investigators and clinical research scientists involved in clinical development. Furthermore, improvements in regulations will drive more interest in conducting development in India.

A key factor driving interest in India is of course the cost – it's still significantly less expensive to conduct trials in India than in western countries. Another key factor that attracts local and global pharmaceutical companies is the large population. The diversity and size of the population means you have an attractive patient pool for a wide array of therapeutic areas. There is a high incidence of disease common to both established and emerging regions for clinical development.

There are an increasing number of well-equipped hospitals, especially in top tier cities. There are also a large number of highly skilled medical personnel, as well as state-of-the-art medical centers that can contribute to biomedical advances. Western trained doctors bring back standards and guidelines to India.

India has a dynamic and motivated English speaking workforce. As India operates in the English language this is a great advantage in development, as most documents can be maintained in English, so there is minimal translation work. There is a focus on producing high quality data. We have seen progress in the data management discipline with an increasing number of clinical trials that include data management performed in India.

Many Asian governments are actively promoting their country as a destination for clinical trials. In India however, we can see some reservations from the government, and the regulatory framework is still being defined. Could I have your assessment on the current regulatory environment to conduct clinical trials in India?

Just like in many emerging markets, the Indian government wants to ensure patient safety and that biopharmaceutical development will benefit Indian society in general. The regulatory framework is starting to evolve and the focus has been on aligning with international standards .

The DCGI made progress in changing its framework. For instance, the clinical trial inspection program has been implemented, and regulators have been working closely with the FDA to have their own inspectors trained.

What is your viewpoint on site quality in India?

With regard to site quality, it is important that a best-practice framework is in place, including well-educated staff, a suitable training environment in both processes and regulatory aspects, and that there are sufficient quality control processes in place. There are initiatives to align India's biopharmaceutical industry even more with ICH-GCP standards, and this has been instrumental in advancing site quality overall.

What are some key growth drivers that will have an impact on various areas of clinical research in India?

Overall, patients can be recruited quite quickly in India. There is an increasing middle class and the Indian population is genetically, culturally, socially and economically diverse. All of these factors continue to make India an attractive hub for domestic India companies or global companies to conduct clinical trials..

Additionally, as global regulators, including the FDA, accept data of global trials involving Indian patients, India will continue to be an attractive geography in which to conduct clinical trials. Furthermore, activities such as data management can be done at a lower cost in India, as compared to other countries. Data management is seen as a well-respected career path in India. There is a vast, trained, English speaking resource pool with a strong understanding of the discipline. Also, there are many data management institutes in India that train graduates, which makes it an attractive market for talent recruitment. These benefits have factored into PAREXEL's strong data management capabilities in India.

What technology capabilities does PAREXEL have that contribute to the enablement of clinical development?

PAREXEL has a market –leading eClinical technology platform combined with proven clinical processes, which assist our clients in speeding development and reducing costs associated with clinical trials, while delivering a high level of quality and innovation. Leveraging our global resources and worldwide technology infrastructure, we can enable more effective information flow and improve data access, which results in greater visibility into trials—and ultimately in better decision making.

How would you describe PAREXEL's market positioning today?

We have had a relatively long-term commitment to conducting high quality clinical trials in India. PAREXEL continue to expand its resources and capabilities in India. PAREXEL has a truly global footprint, and a broad range of development and commercialization expertise to help locally-based companies in India achieve global market access and global companies include India in global development strategies.We are also a leader in providing new partnership models that blend sponsor and service provider resources for maximum efficiency. Biopharmaceutical companies need the help of partners to succeed in today's complex global marketplace. PAREXEL provides

the experience and integrated resources to help our clients improve early-stage decisions, accelerate pivotal trials, reach new markets and leverage technologies for increased operational quality and efficiency.

You have worked on a previous assignment in Shanghai where you also had to face high attrition rate and a “talent war”. How is it to be a PAREXEL manager in India?

As we are growing throughout the Asia/Pacific region, e are focusing efforts in the region on recruiting and retaining the best talent, and our global presence is a real asset for attracting new employees to PAREXEL. Our training gives employees international exposure. We place a lot of emphasis on our global training and development programs.

What is you final message to our readers?

India offers an excellent clinical trial environment. The country is maturing at a rapid pace for all the reasons we have mentioned earlier, which makes a very attractive choice for clinical trials. For us, India is and will remain an important geography to assist our clients in accessing diverse populations, reducing study costs, and conducting high-quality research worldwide. We are focused on assisting the local market with opportunities for market access to bring safe and effective treatments to patients sooner on a global basis.

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