



India: The Place to be for R&D

Despite challenges in sample handling and training, benefits of being in India trump risks

R&D Directions

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Ireland-based contract research organization Icon Plc., like most globally positioned CROs, is actively pursuing outsourcing opportunities in Asia Pacific, with a particularly keen eye on the fast-emerging Indian R&D market. Icon (iconplc.com) has operations in 14 countries in the region, including a fully owned central laboratory in Bangalore, India. The company also has facilities in Chennai and New Delhi, India, and employs more than 460 people in the country.

Icon has particular expertise in managing oncology, cardiovascular, central nervous system, and metabolic disorder trials in Asia Pacific. Studies range from small local trials to pan-regional and large global programs and are supported by Icon's central laboratory in Bangalore and another one in Singapore.

The 15,000-square-foot facility in Bangalore opened in November 2008. The laboratory offers safety, esoteric, and custom-developed assays, including flow cytometry.

R&D Directions spoke with Icon executives Tom O'Leary, senior VP, data management, and Larisa Singh, senior director, clinical operations-India, about the benefits and challenges of conducting medical research in India.

Q: What are the major problems you have encountered with the Indian market?

A: (Mr. O'Leary) Although offering a number of advantages, there were some challenges, which we had to overcome when setting up our central lab in India. One of the biggest challenges is sample handling due to the hot climate, which makes it difficult to transport samples while maintaining an appropriate temperature. This had an impact on selecting a suitable location, which had to have reasonable proximity to the main centers where clinical trials are conducted and also have good transport links and shipping services so that samples can be quickly transported to the laboratory.

The increased complexity of the range of test procedures that are conducted means that staff training is critical. Some testing, such as flow cytometry, was not routinely conducted in India, and therefore technical expertise was lacking.

Q: What other specific obstacles does working in India create?

A: (Ms. Singh) The drug development process varies slightly from other places in the world but the gap in knowledge and experience is decreasing.

Q: How have things changed to decrease the gap?

A: (Ms. Singh) The regulatory agency in India is working hard to streamline its processes and upgrade standards by acquiring the technical know-how and best practices of other advanced regulatory bodies. As in other regions, the clinical research industry complies with [International Conference on Harmonization and good laboratory practice] guidelines.

Q: What factors make India an attractive market for conducting clinical trials?

A: (Mr. O’Leary) Most importantly, perhaps, is the large pool of treatment-naive subjects in a number of therapeutic indications, including both chronic and infectious diseases. For example, India has the largest diabetic population of any country – approximately 40 million people – has more than 30 million people with heart disease, has more than 10 million with various psychiatric disorders, and has large populations of patients with obesity and respiratory diseases. In addition, the country has one of the largest populations for infectious diseases such as tuberculosis, malaria, and HIV. Subject recruitment is reasonably easy compared with many countries, as many people cannot afford to pay for healthcare so readily volunteer to participate in clinical trials in order to receive free treatment.

Another significant factor is cost, and India is one of the most cost-effective countries in which to conduct clinical trials. According to a RNCOS [Industry Research Solutions] report in 2009, India offers substantial savings in both staff and utility costs. For example, salaries for clinical research associates are approximately 13% of those in the U.S. and 17% of those in the U.K., while those for biostatisticians are 15% of those in the U.S. and 17% of those in the U.K. It is estimated that pharmaceutical companies and CROs can realize cost savings of 50% to 75% by conducting clinical trials in India. Other factors that have led to clinical trials growth include language – India is the largest English-speaking country in the world – and the availability of a well-developed healthcare system, well-trained healthcare professionals, and well-educated technical staff. The implementation of legislation to grant patent protection for medicines in compliance with the World Trade Organization Trade-Related Aspects of Intellectual Property Rights in 2005 has also been an important factor.

From a logistical point of view – which is important when operating a central laboratory – there are reasonable logistics with an adequate rail and road network in India.

Q: What influenced Icon’s decision to become heavily involved there?

A: (Ms. Singh) Icon has had a presence in India since 2002. There were a number of factors that influenced Icon’s decision to pursue development activities in this region. They included client interest in conducting clinical trials in Asia – a large patient population that gives faster enrollment and increases the overall speed of drug development, a key benefit in delivering cost savings for our clients – and access to treatment-naive patient populations. This also increases the speed of drug development, as well as enabling the evaluation of some treatment regimes not easily tested in other countries. Also important is the quality of trained investigators, many with U.S. or European degrees, and a well-educated nation that is working to become one of the key players in the drug development arena