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'We have no plans to leave India'

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Located in Bangalore and Maryland, USA, EMMES Services, a contract research organization, set its foot in India in 2006, with a mission to contribute to India's public health challenges and the clinical research as a whole.

Trials in turmoil

The company is backed by strongly skilled professionals including statisticians, epidemiologists, biomedical scientists, data management and information technology professionals, and support personnel, who are necessary to initiate and complete all aspects of clinical projects.

"In 2006 the clinical research environment was very different. Eighty percent of our work in the US are through national institutes of health. Often they carry out global trials, and sometimes in partnerships and collaborations with biotech companies and the industry, or at times on their own. Now, things have changed in India. But having an India office has helped us even in the US. We would like to create relationships with people that will be long-term, and show our value by working along with them," explained Dr Anne.

"It is an unfortunate occurrence. Things can be much more streamlined. The population here still has public health needs and requires access to medicines. I'm confident that as we move forward things will work through, and again we'll be able to have clinical trials in India more efficiently through the regulatory process," she added optimistically.

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Pulling out of India

The change in the regulatory process is an essential requirement as it has big effects on CROs. As a result of unclear, stringent and impractical regulatory guidelines, many CROs pulled out their operations out of India, and others moved to Eastern Europe and different countries which have simplified clinical research regulations.

"We have no plans to move our operations to other countries. We feel that India is an important place to stay. We think that, besides pharma, there is potential opportunities in helping physicians at hospitals, addressing public health issues, learning risk factors for diseases in the country and improvising care. It's a matter of time. We are not trying to become the biggest CRO in India, but rather, we want to be the most important, and improve the health scenario in India," Dr Anne asserted.

Numerous CROs have also knocked on the doors of China because of its simplified regulatory process.

"Middle Eastern Europe is another place where people are researching in this area. India is working on its own regulations and when it is complete, it will be much easier. We understand it is going to take a long time and we are here for long-term. Even in this regulatory situation, we can still contribute to hospitals for pragmatic studies that may help understand risk factors, improve public health, and how it impacts the outcomes of the patients," she stated.

Clear regulatory path

She held that a more pragmatic approach is what will propel the future. "It should all come back to a rational approach with proper monitoring ensuring human subjects are protected appropriately for the research that they are volunteering to do," she remarked.

According to her observation, providing a very clear guidance in how to get through the regulatory hurdles to launch a trial seem to change frequently in India.

Despite the looming uncertainties, she confidently voiced, "Soon we are hoping that this will become clear to companies as to what needs to be done, or even chart out the steps needed to be taken by national institutes in the US to partner, so that it is a fair and plain field for everybody."

Most CRO clients' hope to get assisted in terms of getting through the regulatory hurdles.

"That's a challenge for any CRO because the rules here keep changing," Dr Anne noted. "Our strength is that we have a very strong root in biostatistics and analysis. Armed with that, we can help various organizations in India for consulting, analysis, providing publications with data from India, and provide directions for the next steps in healthcare."

Entrepreneurs & innovators

The company's clients in India are a mix from biotech firms to mid-sized pharma organizations. It has also worked much with government agencies, both in the US and India.

As for EMMES, collaboration, certainly, is one of its important goals. "We are ready to carry out clinical trials or research, which could be a longitudinal study or observational, and not just about getting drugs approved," Dr Anne said.

EMMES, in the US, has been around for 38 years, and has carried out over a 1000 clinical trials in 40 different countries in multiple disease areas. It directly works for 12 of the 27 national institutes of health in the US.

Dr Anne has visited Indian incubators and have been impressed by the country's investments in young budding entrepreneurs with great ideas. "That's an area where we can work along with those entrepreneurs in developing their ideas further. One of things that would make India a leader is the support of entrepreneurs and innovators in the biosciences," she emphasized.

Research in US vs India

Hailing from a rich experience in the US, Dr Anne noted that the funding mechanism in India is different from what it is in the US.

"In the US, there is government funding, and it is very clear as to how to gain access to those fundings. The amount of fundings available for public agencies in India is very less. The regulatory environment further bolsters the hurdles. So funding and regulatory are very much a big differentiator between the two countries. Thus, launching a trial in India is tougher than in the US," She stressed.

India has a great diversity of population, not only in terms of genetics, but also in access to care and information, both at patient level and physician level.

She observed that a lot is being done in India to create centers of excellence to train investigators on evidence-based approach as they gear to tackle health problems in India.

"In the US too, we haven't solved the same problems completely either. But in India it is at a different scale. I'm very encouraged to see how much the government is taking interest in trying to improve in these areas. And we want to be a part of these developments," Dr Anne opined.

Growth drivers

Dr Anne highlighted that EMMES, unlike other CROs, is not driven by randomized clinical trials.

"What drives us is carrying out research that has results, and can be published in scientific literature that will change practice. When the regulatory hurdles in India changes, other CROs are going to come back here, but we are going to stay the same and our mission is not going to change. Our drivers will be the investments that India is putting into entrepreneurs and innovators. Regulatory should see to find a proper balance in patients' safety, and yet not shutting enterprises, which we have witnessed in the last few years," she said.

Organic plans

"Getting to be known is a major challenge," she said while speaking about market entry challenges in India. "It has been 9 years in India, and we are getting to know the challenges. The challenge are getting a foot-in-the-door. This will improve and we'll gain momentum as we work in India."

Dr Anne expressed her excitement about the opportunities in India and her organization's role in contributing to its public health.

"Our future plans are organic, and to meet as many like-minded institutions and researchers to develop relationships, and enable our staff to do more that will impact the Indian population. That's our mission and goal," She ended.