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'We look forward to achieving 35 percent growth'

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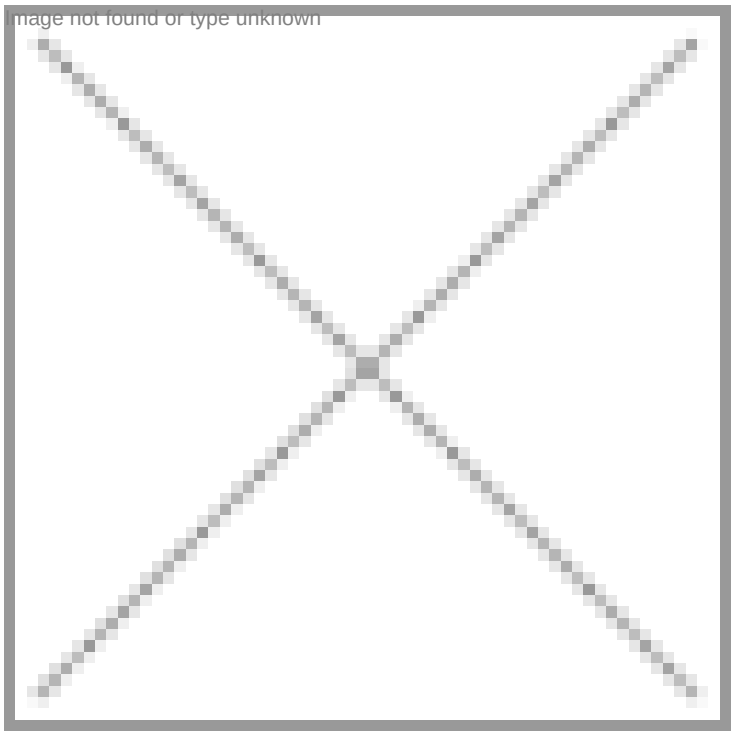

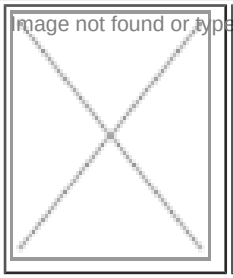

Mr Anil Panwar
CEO, Fortis Clinical Research

Established in 2005, the Fortis Clinical Research Limited (FCRL) is a full service contract research organization based in Faridabad, Haryana. The company is focused on facilitating drug development efforts of the pharmaceutical, biotechnology and device companies across the globe. The FCRL is part of Fortis group, which is promoted by Mr Malvinder Mohan Singh and Mr Shivinder Mohan Singh. In an exclusive interview with BioSpectrum, Mr Anil Panwar, who has recently taken over as the chief executive officer of Fortis Clinical Research, shared his views on the company operations, challenges and the outlook of the company.

Q What edge does the FCRL have over other players in the CRO space?

Mr Panwar: There are many areas where we are ahead of our competitors. Our central laboratory was India's first to get ISO 15189:2007 NABL and CAP accreditation. We have 45 laboratories across India with 1,200 collection centers. We also have experience of over 550 clinical trials for over 35 therapeutic segments. We have a 24-hour dedicated sample archiving facility, dedicated clinical research service department and real time web-based online reporting systems. We extend the

services to about eight million patients annually. The FCRL team excels in end-to-end management of phase I, II, III, IV trials and bioavailability and bioequivalence studies.

Having 55 super-specialty hospital networks with international presence has also helped us a lot. Fortis sites have been the highest recruiting sites in many global studies. We have conducted over 350 studies in the last five-to-six years. Faster site identification and selection due to pan India presence, central lab, and data management smoothens the clinical trial logistic management and operations. Besides that, we have a network of experienced physicians and coordinators across India, which is continuously expanding.

Q What are your areas of strength? What steps have been taken to maintain quality?

Mr Panwar: Our therapeutic expertise lies in the areas of oncology, cardiology, ophthalmology, gastroenterology, and infectious diseases. Our project managers, with vast therapeutic area expertise, have more than seven years experience in study management. Besides that, the team of qualified and experienced employees in operations with medically qualified doctors, look after end-to-end project management and operations. The team has worked on various global clinical trials and successfully cleared many global audits and inspections. We also have the required expertise in developing protocols, manuscripts, clinical study reports with quick turnaround time and focus on quality control.

Our clinical team comprises medical doctors, registered nurses, technicians, and medical assistants who have expertise in conducting phase I studies irrespective of the fact whether the volunteers are healthy or patients suffering from various ailments. We have also got expertise in end-to-end management of phase II–IV clinical trials. To support the clinical data management and biostatistics services, we have SAS programing with a data management team, including biostatistician, SAS programers, quality auditors, medical data validation and data entry operators.

Our company has been approved and audited by regulatory agencies across the globe. These include the approval to conduct BA/BE studies by the DCGI (India) in January 2006. The company was audited by it on January 2011. Audits were also done by AFSSAPS (France) in February 2008, ANVISA (Brazil) in March 2006, August 2007 and August 2009. The USFDA has also successfully audited us on July 2010. The experienced quality assurance professionals at the FCRL work with clients to conduct internal and external GCP audits. All studies performed are audited by our quality assurance department according to the FDA regulations and the ICH-GCP guidelines.

Q How do you visualize growth of the CRO industry in India?

Mr Panwar: The industry is growing at a good pace. The size of the industry is roughly estimated at 3,000 crore. It is growing at an annual growth rate of 20 percent. The major advantages in India are cost-effectiveness, knowledge and availability of cheap manpower. However, it is yet to reach a level that was expected. The expectations have not been met because of certain issues. Among these are the unavailability of enough qualified manpower, mushrooming of unethical CROs, unwanted delays in regulatory affairs and competition from other countries. Therefore, we need to evolve fast and catch up with the competition that may overtake us completely, if we do not address the issues proactively.

Q What challenges does the Indian regulatory structure pose for the clinical trial industry?

Mr Panwar: The regulatory process needs to be changed and enforced strictly. There is a huge requirement for changes. It is understandable that healthcare had taken a back seat earlier because food and shelter were the primary focus areas. However, with the increasing income levels, there has been a major shift towards addressing the healthcare needs of the masses.

The government can train people in e-filing and they also need to adhere to timelines. On the part of the industry, we must also gear up and start discussing with various government agencies. Our associations need to play a more active role now. The major challenges include delays in approvals. The mushrooming of a few small unethical CROs are bringing a bad name to the entire industry. A minimal qualification should be there for the establishment of CROs and a basic standard has to be set so that people do not come into this line only for business interests. The lack of enough inspectors in India is also one of the issues that needs to be looked into by the government. There is the need to provide international exposure to these inspectors. Electronic filing with the DCGI must be welcomed.

Q What is your response to allegations that informed consent is not taken by CROs before trials?

Mr Panwar: There may be some unethical small-time CROs who do that but the big and responsible CROs never indulge in such actions as it is not good for their well being. In our case, we take extra precaution while going for trials. We inform the patients well in advance about the consequences. The patient is offered a free healt check-up and, on the basis of that, it is decided whether to go ahead with the trials.

We also need to be conscious of the fact that the patient might, at times, be uneducated and, therefore, to overcome the

communication gap, a person of the same language or background is used as an interpreter to convey the message. Doing the video recording of the entire process is also an option that can prove helpful in this regard.

Q Where do you see your company five years from now?

Mr Panwar: We will be looking forward to achieving close to 35 percent growth in the coming years. I wish to see the company occupying the top position in the CRO space in due course of time.

— Rahul Koul in New Delhi