

JCDC accredited to carry research on humans

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Pune-based Jehangir Clinical Development Center (JCDC) was formed in 2006 to focus on clinical trials. Since then, the company has achieved several milestones, with the most recent being the accreditation from the Association for the Accreditation of Human Research Protection Program (AAHRPP).

The accreditation is the latest indication that organizations are embracing AAHRPP's goal of establishing a single set-of-standards worldwide for CROs, independent institutional review boards, research-intensive universities, medical colleges, hospitals, and other entities that are engaged in research involving human participants. JCDC is the third institution in India and seventh in Asia to attain the AAHRPP accreditation. BioSpectrum talks to Mr Pathik Divate, CEO, JCDC, regarding the major achievement of his firm and the future plans for the company.

Congratulations on receiving the accreditation from AAHRPP. Please tell us about the importance of this milestone for JCDC?

We are very pleased to receive this accreditation. It is a stamp of approval from a very renowned and reputed accreditation body, which is gold standard for research centers all over the world. This accreditation recognizes that we have the right procedures in place for research. Currently, there is a lot of debate in the country whether human subjects participating in clinical trials are adequately protected. Since AAHRPP's main focus is the human research protection program, we are sending out a clear message that we are following right procedures for clinical trials.

We are the third institution in India and seventh in Asia to receive this accreditation. Manipal hospital in Mangalore and Bangalore are the other two that had earlier got this accreditation. This accreditation is meant mainly for research centers and hospitals. All the big research centers such as Harvard Medical School and Massachusetts General Hospital among others have this accreditation. The accreditation puts us in their premier league.

Please tell us in brief the procedure involved in receiving this accreditation?

The entire procedure involved four steps. In step I we had to send all our Standard Operating Procedures (SOP) to the association. We had to provide detailed answers to around 70 elements that were divided into three domains. We gave

suitable answers with various documents explaining how we were taking care of various aspects in these domains.

The authorities then asked for further clarifications about certain procedures. Step II involved providing the replies to the questions that were raised and taking corrective actions wherever necessary, within a given timeline. Step III was a two-day site visit by two auditors from the US. They interacted with our staff and researchers, including the ethics committee members and everyone involved in the research process. They also did a random sample check of various documents requested by them. Post auditing, there were minor observations, for which we had to take corrective action (step IV) and then, finally we got the approval. The entire process took little more than a year.

What are some of the steps taken by JCDC to set itself apart from other CROs in India?

Since we started in 2006, we have set ourselves apart by setting up a one-of-its-kind research center. We are situated within the hospital premises and we have committed infrastructure and people to focus on research. Besides, sponsored clinical research from pharma companies and CROs, which consists largely of phase II and III studies; we conduct investigator initiated research that is basically original research.

Please tell us about some of the recent achievements of JCDC in the CRO domain?

We work with nearly all the top 10 pharma companies worldwide. We had awarded the best clinical research investigator site in 2010 by the Indian Society of Clinical Research. We are also ISO 9001 certified. We have diversified into the education space by setting up a training center. We also do medical writing work, monitoring, and data management for some of our clients. We don't position ourselves as a CRO but we have capability of doing CRO work and can provide end-to-end services. However, our main focus still remains on providing high quality site management services.

What are your plans for the future?

We are serious about clinical research and want to grow in this field. We are tying up with hospitals for providing site management services in India and abroad. We have also set up a dedicated research laboratory and are looking to grow our training division to create more branches in India.