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Axis turbulence hits India's CRO industry

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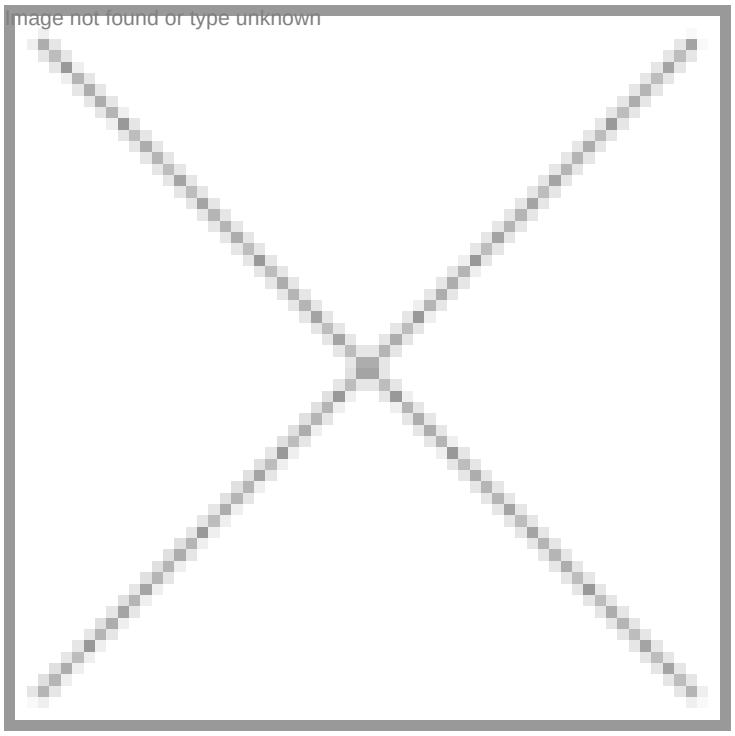
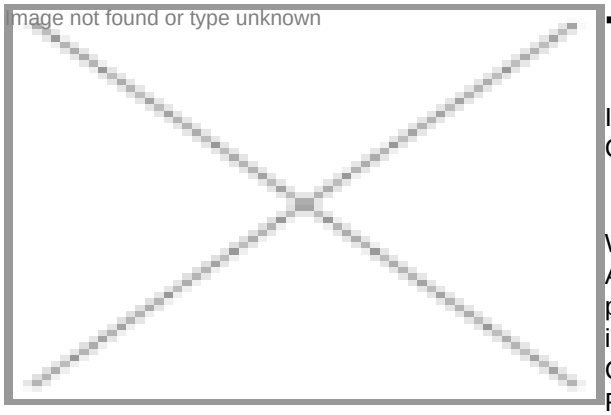


India's fast-growing CRO industry is apprehensive of a backlash against the sector after the regulatory action taken against Axis Clinicals for its misconduct



The regulatory action to shut down the key operations of Hyderbad-based Axis Clinicals over unethical practices detected in its recent clinical trials of an anti-cancer drug, has sent shockwaves through India's 3,246 crore(*BioSpectrum*-ABLE biotech industry survey 2011) CRO (clinical research organizations) industry, just when it was angling

What has come as a major shock is that the delinquent CRO company, Axis Clinicals is closely associated with one of India's well-respected pharma majors, the 4,381 crore Aurobindo Pharma. Axis Clinicals, incorporated in September 2004, is promoted and run by Mr Sarat Chandra Reddy, son of the Aurobindo Pharma's chairman, Mr P V Ramprasad Reddy. Though Axis is not a group company of Aurobindo Pharma, the younger Reddy is a non-executive director on the board of the publicly-listed pharma major.

The issue led to an emergency meeting on July 29, 2011 of the Association of Clinical Research Organization (ACRO). Industry leaders have come out in full support of the regulator's stringent action which was required in the overall interests of the industry. At the same time, the Association requested the government not to harm the industry's interests due to the actions of one black sheep in the sector.

Axis is not an associate company of Aurobindo. But Axis is treated as one of the enterprises in which Aurobindo's key management personnel or relatives exercise significant influence. BioSpectrum's attempts to get Axis' side of the whole issue so far has not materialized till the time of going to press.

Following media reports about the unethical practices of Axis Clinicals, the regulator, the Drugs Controller General of India (DCGI), suspended the operations of the Hyderbad company. Axis has been banned from conducting bio-availability(BA) and bio-equivalence(BE) studies at its Miyapur center in Hyderabad. The company was accused of following incorrect patient enrolment process, trials without prior consent and use of a non-independent experts committee to oversee clinical trials.

Though the company conducts over 70 trials in a year, what has got Axis Clinicals into trouble is the use of poor women as subjects in the trial for anti-cancer tablet Exemetasane conducted from January 27 to February 15, 2011, in Piduguralla town of Andhra Pradesh. Apparently, the women volunteers were not informed about the true nature of the study.

What is troubling the CRO industry is that this particular incident has made the regulator look at the entire industry with distrust. Approval for routine clinical trials are not forthcoming as the regulator takes a cautious stance. The bad news about Axis has spread far and wide and the Indian clinical trials industry is now looked at with suspicion by sponsors.

â€œThis incident has badly affected the industry like never before. For the last two months, things have been moving very slowly and new permissions for conducting studies have not been given. The DCGI is now asking for more data, stability reports and more additional information,â€? lamented industry veteran S P Vasireddi, CMD of another top CRO, Vimta Labs, Hyderabad.

Mr Vasireddi feels that the Axis incident has been hyped up by the media and the involvement of human rights organizations, politicians, middle and senior levels of bureaucracy have added new dimensions to the problem.

The regulator is quick to allay the fears of the industry. When contacted by *BioSpectrum*, Dr K Bangarurajan, deputy drugs controller of India, New Delhi, informed that only one company (Axis Clinicals) was suspended from conducting all BA and BE studies at its center in Hyderabad. â€œWe have not suspended other firms from carrying out clinical trials in the country. However, he added, â€œIf DCGI receives any complaint against any firm violating the rules, we will act upon it.â€?

â€œThis move has definitely impacted the CRO industry in India because post this incident, the DCGI is not giving any approval to conduct bioequivalence studies for foreign companies. Companies in India mainly depend on foreign clients for their business,â€? said Dr Arun Bhatt, president, Clininvent Research, Mumbai. As far as corrective measures are concerned, he said, â€œThere are three aspects that need to be seriously looked upon by the DCGI- the methodology registration of trials, regular inspection of sites by inspectors and lastly, an independent ethics committee.â€?

While the industry is worried about the immediate slow down on approvals of clinical trials in the short term, there is considerable support for the regulatory action which is seen as a long-needed corrective measure.

â€œIt is good for study participants, CROs and sponsors that the clinical trial practices are being checked. It is expected that if gaps are found, there is an opportunity and reasonable time given to the service provider to explain. Sensationalizing the action of a few non-compliant units and ignoring good compliant work being done by most CROs should be avoided,â€? said Mr D A Prasanna, CMD of Ecron Aucnova, Bangalore. â€œEthical testing is essential to bring new drugs to market. India is playing a big role bringing cost-effective drugs to the patients in India and the world. Such work benefits society and we need to encourage the same in India and in the world,â€? he added.

Dr Milan Satia, CEO, Ethicare Clinical Trial Services, Ahmedabad said, â€œThe decision probably is right and this is a step forward for implementation of Good Clinical Practices in the country. First step should be self-disciplinary approach by CROs towards the implementation and management of all good practices because they are playing with human life and therefore, utmost care in every aspect is required.â€?

Axis had a seven-member ethics committee comprising three doctors, two scientists, a lawyer and a company official as member secretary. When contacted Prof P Reddanna, who was one of the members of the ethics committee of Axis Clinicals for the last three years, said, â€œFrom recruitment of volunteers to data gathering process, we ensure that all guidelines are adhered to.â€? Prof P Reddanna, who is currently heading the National Institute of Animal Biotechnology, a central government initiative, as officer on special duty, raised doubts about the role of some NGOs, and observed â€œThis is because of a misconception among the public about BA and BE studies and clinical trials. And people, who are in need of money are re-registering as volunteers in less than three-to-four months.â€?

Another ethics committee member, Mr Ramakrishna, who has been working as secretary of the ethics committee for the last seven years with Axis Clinicals said, â€œSo far, Axis Clinicals has done over 350 BE/BA studies since 2004 for Indian and

foreign pharma companies. The committee, headed by Dr N Srinivas Rao, professor of medicine, department of general medicine, Osmania Medical College, used to meet two-to-three times in a month. During each meeting the committee used to approve two-three molecules for conducting studies.â€?

The turnover of Axis Clinicals in 2010-11 is estimated to be a round 70 crore. Nearly half of it, 34.46 crore is from Aurobindo Pharma for clinical services provided to the pharma major. This was a 12-fold jump over previous year's 2.7 crore business from Aurobindo. Interestingly, Axis Clinicals trumpets that it has state-of-the-art facilities with 500+ dedicated full-time professionals to ensure quick turnaround time with high quality. Its facilities are accredited by DCGI, NABL (National Accreditation Board for Testing and Calibration Laboratories) and inspected by US-FDA, UK-MHRA, Brazil-ANVISA and France AFSSAPS and conforms to ICH and CDSCO-GCP & GLP Guidelines. The firm further noted that it has completed more than 10 years of regulatory audits from global competent authorities till mid-2011.