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Caught in crossfire?

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Caught in crossfire?



As per records of the Drugs Controller General of India (DCGI) in the Supreme Court, India approved 475 clinical trials for 'new chemical entities' not used as drugs elsewhere in the world between January 2005 and June 2012. Further, the documents submitted by the DCGI claim that 11,972 adverse effects, excluding deaths, were reported in the period, with 506 of these being directly attributable to the trials. They put deaths from trials at 2,644 over the last five years.

The mainstream media reports from time to time displaying prominent headlines on the clinical trial deaths, have brought a bad name to the industry. And experts also lament that most of these alleged deaths are not even actually related with the trials. It is now clear that as far as opening a dialogue and establishing trust is concerned, there a big disconnect between civil society and industry.

While the civil society and media representatives say that its their duty to uphold the human rights, Dr Renu Razdan, chief operating officer, Max Neeman International feels that hype and sensationalism won't do any good. She says, "Unfortunately, the regulatory response to such media reports has been reactive making the e-regulatory process for clinical trials slow and uncertain. There is also a lack of transparency and consistency which is a cause of concern for the clinical research professionals in the country."

The availability of volunteers which was once feared to be a major concern is now no longer among the immediate issues. Few industry experts feel that word 'volunteer' in this context is flawed in itself. "People participate for money. With high compensation there is no dearth of healthy subjects," remarked a prominent person from industry. He added further, "It was never and will never be a variable hampering clinical trial growth in India. India never lacked the availability of volunteers for doing trials. In fact, the availability of volunteers will always hinge upon the proper and scientific counseling of the patient to take up decision about being a part of clinical study or not."

India has always followed the International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use- Good Clinical Practices (ICH-GCP) processes for informed patient consent. The document "Informed Consent Form" has all the detailed information written in layman and local native language for easy understanding and comprehending the information. Aaditya Vats, manager-regulatory affairs, Excel Life Sciences feels that informed consent is an education and information exchange process between investigator, the subject and their family. "The entire process of consenting gives adequate time and opportunity to the subject to consider all alternative options, consult with family, colleagues and physicians before taking the voluntary decision to participate in the study. Hence with the current documentation practice, if practiced, I don't see any reason for concerns over patient consent," he said.

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Recently the recent draft gazette from ministry of health has contemplated the recording of the entire patient consent process through audio /video by the CDSCO office. But now it being a law for study subject to participate in the study, few are pointing towards challenges in terms of maintaining confidentiality of the subject and logistics of recording etc. "While this is a welcome move, it will have its own set of challenges in execution, including protecting patient identity, review of informed consent tapes, consent for video consent etc. While defining clear cut processes is one part of resolving the problem, the other more

important part is rigorous execution and oversight. One can only wait and see if this move will have a long term impact," says Nidhi Saxena, chairman and chief executive officer, Karmic Life sciences.

Agreeing Dr Mita Nandy, chief operating officer, Fortis Clinical Research, feels more positive about the change. She says, "In India Â mostly the patients with low socioeconomic stature to obtain treatment benefit Â participate in trials. This is fact and hence inducement is doubted by foreign sponsors or regulatory bodies. To take care of this consent process should be taken in details using audio video recording which will definitely help to obviate the doubts global sponsors/regulators have regarding the consent process in India."

Recently during a workshop on regulatory changes, organized at Jamia Hamdard University, various industry experts had expressed their resentment against what they called lack of clear decision making on part of DCGI's office. Notwithstanding the criticism, Dr GN Singh had clarified that though there are challenges but that doesn't mean that regulator can take only one sided approach. He had maintained that efforts are on to build the required manpower and infrastructure in due time to mitigate the concerns. He also had pointed toward the lack of staff (especially drug inspectors) at the regional regulatory offices as well as the CDSCO. Meanwhile recently, the organization has recruited close to sixty new inspectors and are also looking at strengthening the manpower and infrastructure.

DCGI's office has also started meetings with the various stakeholders to since January this year. On being asked about the same, Dr Singh had told BioSpectrum, "I wanted to get updated on the reactions of patients and all the other stakeholders on the clinical trial system. In that direction, we initiated meetings with common people, manufacturers and civil society members from time to time. Since the civil society represents the aspirations of people, we would like to work closely with them. In fact, the mistrust that existed earlier has evaporated gradually. I think this is the time to build up expectations and regulator must know that. It is the high time to build up the confidence among the public that we are there."

With reference to minutes of the Drug Testing Advisory BoardÂ (DTAB) meeting held on May 16, 2013 which discussed the compensation guidelines, the Indian Society for Clinical Research (ISCR) in its statement mentioned, "This is an encouraging development and we are glad that the regulatory bodies are addressing the concerns of all stakeholders. Collaboration, transparency and open dialogue are important to ensure the progress of the industry, while securing the rights and safety of patients."
The president of ISCR, Susheela Thatte, mentioned, "We believe the media can play an important role in highlighting the impact the new rules are likely to have on clinical research in the country and particularly the innovative, indigenous research that is being carried out in several academic institutions and teaching hospitals."

At present, we are just a miniscule part of global trials. This is despite the fact that our country accounts for about sixteen percent of the world's population and close to twenty percent of the global disease burden. Hence, there should be little doubt that the sector cannot be ignored anymore due to the standoffs between various stakeholders. Time is right to open have much better and effective communication channels and quick response mechanisms to mitigate the concerns of all of them. The industry too has to make efforts to undergo an image makeover by making connect with people and be humanitarian in its approach.

Lack of clarity on new regulations?

Ã¢â??Â Injury occurring to the clinical trial subject be given free medical management as long as required.
Ã¢â??Â Any injury or death shall be treated as clinical trial injury or death and entitled for financial compensation.
Ã¢â??Â Absence of arbitration mechanism in case of disagreement on causality/quantum of compensation.
Ã¢â??Â On who shall be in the expert committee constituted by the licensing authority.

Way out

Ã¢â??Â Establishing a progressive regulatory framework incorporating patient care.
Ã¢â??Â Subject compensation and clinical trial norms and uniformity with globally established standards.
Ã¢â??Â Better clarity on the compensation rules and ethic committee.
Ã¢â??Â Entering into a mature dialogue with media and activists.