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Govt strengthens clinical trials regulations

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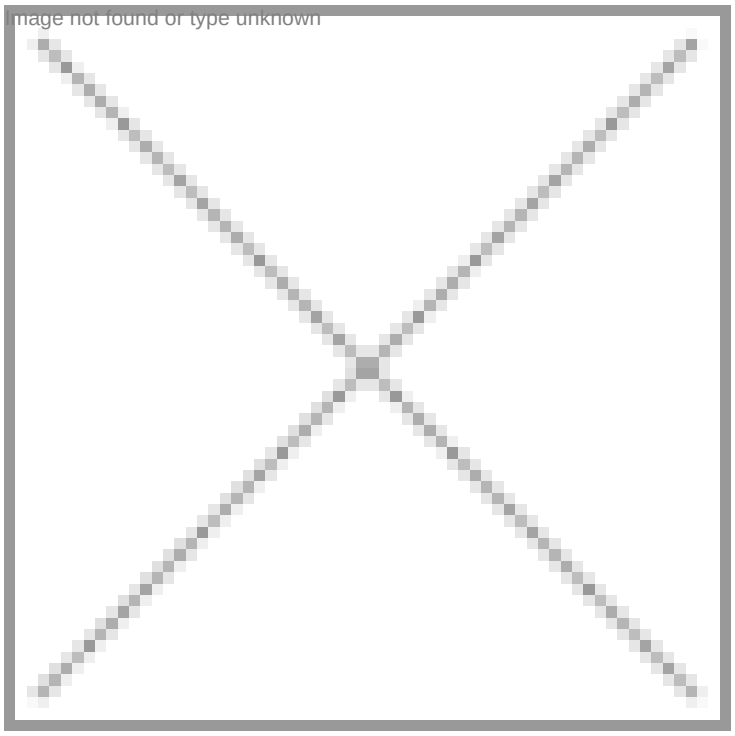

In a bid to strengthen the regulation and monitoring of clinical trials in the country, the Indian Government has announced several measures to strengthen the regulation and monitoring of clinical trials in the country.

12 New Drug Advisory Committees (NDACs) and 6 Medical Device Advisory Committees (MDACs) have been constituted to evaluate clinical trials proposals. These committees consist of leading experts from Central and State Government medical institutions. Also a draft notification has been issued for incorporation of a new rule in the Drugs and Cosmetics Rules, 1945, which addresses issues such as medical treatment and financial compensation to the trial subjects in case of trial related injury or death and the procedure for payment of financial compensation. Also an enhancement of responsibilities of Ethics Committee (EC), sponsor and investigator has been called for ensuring that financial compensation as well as medical care is provided to the trial subjects who suffer trial related injury or deaths and such information is provided to DCGI.

One of the significant measures has been the amendment of the format for obtaining informed consent of trial subjects to include the details of address, occupation, annual income of the subject so as to have information regarding socio-economic status of the trial subjects. Obtaining vital information such as this would go along way in making the clinical trial process more transparent and hence reduce the negative connotations associated with them in the recent past.

India unveils two new PPP programs

Government of India launched two new programs in Public Private Partnership (PPP) mode. The purpose behind thecreation of the PPP programs is to fuel innovation in various technological areas including biotechnology.

The Global Innovation and Technology Alliance (GITA) is a program jointly created by Department of Science and Technology (DST) and Confederation of Indian Industries (CII) which seeks to leverage innovations taking place around the

world by enhancing technology competitiveness of Indian industry and institutions through joint development, technology transfer and joint ventures. Whereas Millennium Alliance program is jointly created by India and the US and the DST is partnering with United States Agency for International Development (USAID) and Federation of Indian Chambers of Commerce and Industry (FICCI) to promote cost-effective and rigorously tested solutions for critical development challenges that have the potential for sustained global impact.

Cipla reduces price of its cancer drugs

Cipla has reduced the prices of its selected cancer drugs for the treatment of lung, liver, kidney and brain cancer. Cipla's Soranib (Sorafenib) will now be offered to cancer patients at a price of 6,840 for a month's therapy instead of the current cost of 28,000.

TB now a notifiable disease

The government of India has declared TB as a mandatory notifiable disease with immediate effect. The move comes closeon the heels of the news of suspected TDR-TB cases being detected at a Mumbai hospital a couple of months ago. The notification process hopes to facilitate early diagnosis, rational treatment, prevention of complications, drug resistance and reduce deaths due to TB. It will also help the healthcare providers to offer better linkages for quality diagnostic and treatment services to the TB patients. Most importantly, it hopes to facilitate the National TB Control Programme (NTCP) to realistically estimate TB disease burden, plan resources and control measures that commensurate with the actual burden of disease for larger interest of the public and nation as a whole.

Setting up of state level cells by NPPA

With a view to strengthen the enforcement and monitoring system with the help of State Drug control administration, National Pharmaceutical Pricing Authority (NPPA) has inter-alia proposed a scheme for the 12th Five Year Plan titled, â€œCreation of NPPA State Government Coordination Cells in the States.â€?

The NPPA-State coordination cell in the States will act as a nodal agency to oversee the compliance of drugs provisions in their respective states and will work under the direction of the NPPA. It will also serve as a local point for the consumer to lodge their complaint regarding overcharging, non-availability of drugs and other grievances.