Clinical research in India fast gaining global pace

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GLOBAL pharmaceutical industry is in the cusp of a transition due to several economic, demographic and social changes. Declining R & D productivity and looming patent cliff are threatening the industry along with the changing business models.

India itself has 1/5th of the global disease burden and a large unmet medical needs for the patients. Due to both the challenges, we need to develop new drugs faster. Clinical research is the way to introduce safe and effica-cious drug in the market. Since ages, the available drugs are proved and launched in the market by the way of proper randomized clinical trials only.

Globally, all the geographies have voiced their support for safe, efficacious and cost - effective drug import and this could boost the Indian pharma companies, which supply about 40 per cent of thel generic drugs consumed in the US. India, given its large treatment naïve patients, product development skills, and scientific man power, offer a solution to the global pharma industry to address the challenges of growth and innovation.

With the regulatory overhaul in India, the regulatory frame work has been made more balanced, scientific, proactive and focused on patient's safety and ethics. New initiatives implemented by CDSCO (Central Drug Standardization Control Organization) by realizing the potential and available opportunity in India, along with broader involvement of all the stake holders, the regulatory approval process has became faster, predictable and in line with global practices from all the fronts.

As per the data available from CDSCO website, several initiatives have taken place, such as Public relation office (PRO) functioning as a single window to provide guidance to stakeholders without prior appointment. Nearly 85 per cent applications (all categories) are disposed off regularly on monthly basis. This has lead to a spurt in the approval of clinical trials including global trials.
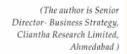
In the last five years, more than 444 applications for global clinical trials have been received and 329 applications have been approved (as of July 2018). And even the average trial approval time, which was around six months earlier, has now become around three months.

Also initiation of e Governance system through "SUGAM portal" for the online application has been really helpful and quick. Apart from that, a separate portal for medical devices has also started. Eventually, CDSCO is aiming to have a single platform for all regulatory requirements in the country.

CDSCO office has prepared a draft "New Drugs and Clinical Trials Rules 2018" that has been published and it is under finalization stage. In that trial related injuries and its compensation has been discussed in great detail for better transparency to all the stakeholders.

An Intelligence cell has been created at CDSCO HQ and one of the major functions of this cell is surprise audits. Audits (all areas GxPs) carried out by CDSCO officials have really helped to enhance the quality at all the levels. In the last three years, during several USFDA/WHO inspections, DCGI officials have accompanied the inspectors to understand the global perspective of audit at several multi-centre sites. This is well appreciated by industry from training and capacity building point. Majority of these investigator sites have cleared the audit without any major observations. This has really helped to establish the trust of global pharma companies about data quality and integrity of sites.

Overall, with all these initiatives and balanced efforts of by CDSCO, keeping ongoing dialogues with all policy- makers and clinical research stakeholders to ease doing business, clinical research in India will definitely meet global standards. This will definitely enhance the confidence of global sponsors, to include India in their global programmes and to receive faster approval of products. ◆

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