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â€œRegulatory changes if implemented, will make us more strongerâ€?

24 July 2013 | Features | By BioSpectrum Bureau

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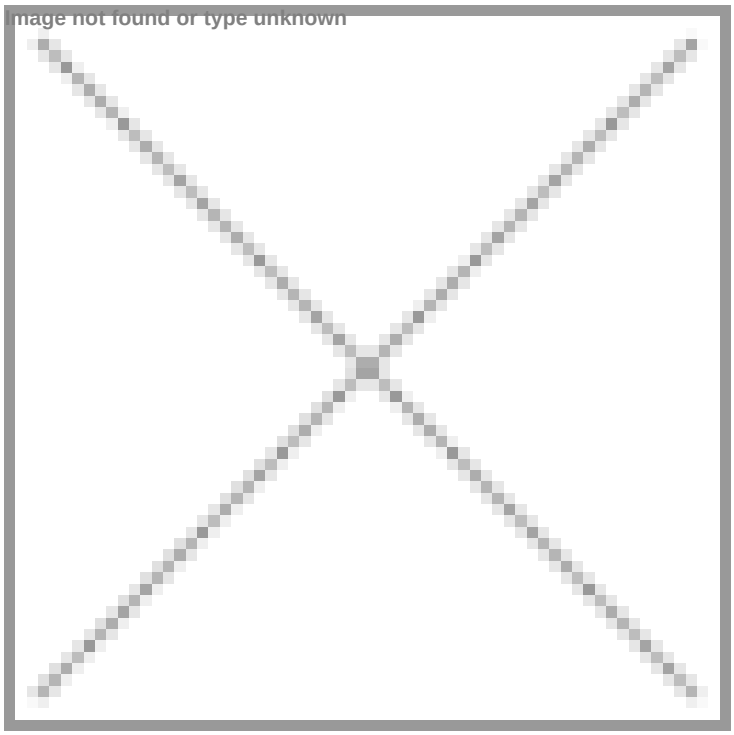

Clinical research industry has been in news a lot lately, and not entirely for good reasons. Although the concerns of civil society regarding the safety and ethicality of clinical trials are not ill-founded, we cannot undermine the indispensability of this field of research for our country, both as a science and as an industry. Annual global turnover of Clinical Research industry is $500 billion in which India has a share of $500 million. Even as a small part of the global business, it has brought much needed revenue to our country. But most significantly it has opened the gates for entry of many life-changing and life-saving drugs into our country. India with its large population of diverse ethnicities, modern infrastructure and trained manpower has been a lucrative choice for pharmaceutical companies.

In India, clinical trials for drugs have been conducted since 1988 when Schedule Y of Drugs and Cosmetic Act became effective. In 2002, the number of trials was 40-50 trials (Centerwatch August 2003). Over last several years the number has increased. In 2009, CDSCO permitted 453 trials (258 global and 195 local). This was mainly due to Indian government making effective regulations - Schedule Y 2005 - and ethical and scientific guidelines - Indian Good Clinical Practice (GCP) and ICMR ethical guidelines- for clinical research. These regulations and guidelines are in line with international regulations and International Conference on Harmonisation GCP guidelines. These statutory requirements improved the quality of Indian clinical trials and made the data acceptable to international regulatory agencies.

This growth of clinical research activity has been of immense benefit to India. Few of the key facts that prove that are:

- Large number of Indian patients have benefited from new therapies for serious conditions such as Cancer, Heart Disease and Infections, debilitating neurological diseases, and the new epidemic of diabetes.
- Indian physicians have received training in scientific and ethical aspects of clinical research. The number of investigators has increased from 188 in 2002 to 1523 in 2008. The research infrastructure has also improved to a great extent.
- Clinical research has become an attractive new discipline. Today, we have a large contingent of trained clinical research professionals - clinical research physicians, regulatory and ethics experts, clinical study managers, monitors, quality assurance and pharmacovigilance experts, data managers, biostatisticians, medical writers, etc.
- Management of clinical trial data has supported growth of Indian IT / KPO sector.
- There have been positive spin offs in allied disciplines leading to expansion of special laboratories devoted to clinical trials, and development of clinical trial packaging and distribution industry.
- All these factors have given tremendous boost to R & D and innovation capabilities of Indian pharma industry and made India an attractive pharmaceutical Drug Discovery and Development destination.

The quality of Indian trials is at par with global standards. Since 2005, USFDA has conducted inspections at 30 Indian investigator sites. There have been no serious non-compliance issues at any of the sites. The data from Indian trials have been accepted by US FDA and European Medicines Agency.
Although there have been some media reports of cases of non-compliance to regulations and guidelines, majority of clinical trials are conducted in compliance with national and international scientific and ethical norms. These deviations point to an urgent need for regulation inspections and training and accreditation of the Indian investigator sites.

Unfortunately, the regulatory response to such media reports has been reactive, making the e-regulatory approval 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.

Recent developments regarding the regulatory overhaul of the clinical trial procedure has slowed down the pace with which the industry was progressing. But gradually the industry and the researchers have started looking at this with some practical optimism. The various measures taken by the government has infused some confidence in the industry, notwithstanding the new compensation rules. The office of Drug Controller General of India has started inspecting and auditing clinical research facilities. This will result in standardization of procedures and also weeding out of elements indulging in unlawful practices. Further, the committee appointed by the government is expected to soon come up with policy guidelines for clinical trials and new drug approvals. The basic purpose of this committee would be to streamline the whole procedure on scientific basis and to achieve this it is taking into account the viewpoints of all stakeholders.

Pharmaceutical companies have their hopes pinned on the recommendations of this committee to put an end to all the negative apprehensions that have plagued the growth prospects of Clinical Research, which is not good for needy patients and industry. To assume that Clinical Research has a bleak future in India would be exaggerated pessimism. No one can deny that new regulatory guidelines would result in an initial slowdown. But eventually it would make our industry more suitable to international business. For example, US FDA audits of clinical trial sites in India have resulted in remarkable improvements in industry standards.

All the factors that helped us establish a clinical research industry in India and lure foreign companies here are still intact. So once the new regulatory guidelines are implemented, all it would do is give more credibility to our research and place us at a more reliable and stronger position.

About Author:

Dr Renu Razdan heads the business development and operations function of the Max Neeman. During the course of her career, Renu has worked at different positions within the company, while dealing with Indian and international customers. She travels extensively to understand customer requirements in various geographies.