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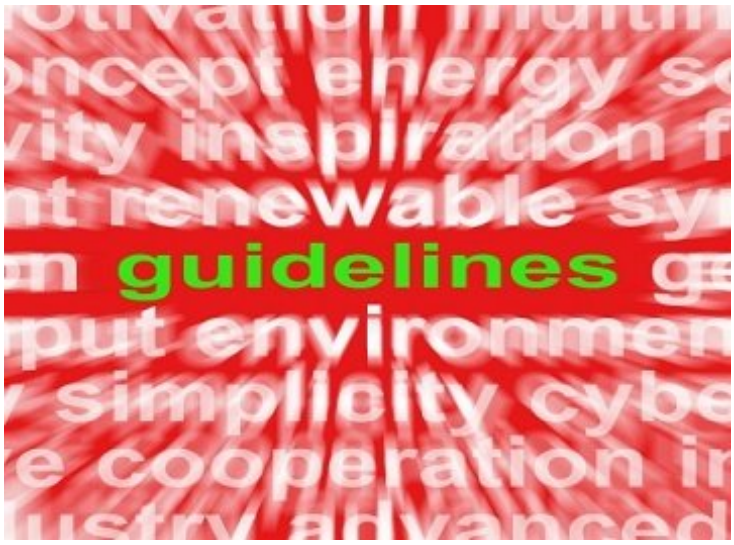

The Indian Clinical Research Industry went through a trying phase in 2013 and 2014. However, 2015 saw steps taken by the Indian regulators to mitigate the challenges posed by regulatory uncertainty and address stakeholder concerns through amendments in regulations, new orders and further guidance on existing ones. Have these new guidelines improved the clinical research scenario? How does the future look for Indian clinical research industry? Read on to find out...

Have the revised guidelines improved the environment?

The most significant of these changes were revisions to the compensation guidelines and audio visual recording during clinical trials which were major barriers for sponsors conducting clinical trials in India.

"The compensation guidelines are now more balanced and rational; we are beginning to see more predictable approval timelines with the expansion of the Subject Expert Committees and the expected roll-out of the accreditation process is projected to have a significant impact on the quality of research," Dr Rajashree Devarakonda, Vice President, India and Asia Pacific, Voisin Consulting Life Sciences (VCLS).

She added, "This is a major improvement from the previous guideline and now this brings India back to almost the same level playground as other global counter parts. In addition, CDSCO has launched a new online clinical trial submission system as part of efforts to increase accountability, transparency and efficiency in processing clinical trial applications."

However, it will take time to see the real impact of these changes although there is already begun a reduction in approval timelines.

"The environment is certainly more positive but rebuilding trust and confidence is a long and slow process. What has been extremely encouraging is the inclusive approach adopted by the Indian regulators whereby stakeholder feedback has been actively sought and acted upon in many cases. We now have a regulatory system that is balanced, aligned with global trends and one that addresses our uniqueness as a country and society. This is a significant development," Ms Suneela Thatte,

President, ISCR (Indian Society for Clinical Research).

India: Numero Uno, Again?

While Indian Clinical research industry was going through a turbulent phase, South Korea (and many other Asian countries) has emerged as the preferred destination for clinical trials. Would India be Numero uno again?

"I would, at the outset, like to clarify that India was never a country that had a very high percentage of trials relative to trials being done in the rest of the world nor is it our objective to be the number one country in the region or globally for doing trials. What is important is that the trials being done in India are significant enough to address our growing burden disease and the unique healthcare requirements of our country." points Ms Thatte.

She further added that the Government of India sponsored Working Group on Disease Burden for the 12th Five Year Plan refers to the "triple burden of disease" that developing countries like ours are facing arising from Communicable Diseases (like TB, Leprosy, vector borne diseases, water-borne diseases, zoonotic diseases and vaccine preventable diseases), Emerging Non-Communicable Diseases related to Lifestyles (like cancer, cardiovascular diseases) and Emerging Infectious Diseases (like Ebola virus, SARS, H1N1). Therefore clinical research in our country is a health imperative and important to the progress of the health of our people and the economy.

"Positive changes around regulatory framework and policies are happening. Changes to compensation issue and audiovisual recording, improved review time of clinical trial application, improved monitoring etc. has slowly started attracting sponsors back from other countries back to India," said Dr Devarakonda.

Attraction of India in terms of its large patient pool, low cost of doing business, availability of expert researchers, and, huge market opportunities still remains. It is very much a possibility for India to regain its position as compared to other Asian countries.

"However, regulatory approvals and extended timelines in clinical trials need a coherent set of stand-alone rules and safe drugs adhering to Good Clinical Practices, the compulsion of conducting clinical trials to improve therapeutics should be effectively communicated to the public, patients, media and policy makers, new regulatory personnel to be recruited and trained on an ongoing basis to meet the growing requirements of clinical trial applications. In summary, capabilities building for development of new drug that can help the country tackle public health challenges," said Dr Devarakonda.

Enabling more trials in India

India has the highest burden of disease in the world, the second largest patient population and yet less than 1.4% of global clinical trials are done in India. What do we need to do to address our triple burden of disease and ensure better, cheaper and more accessible medicines for our population?

"We need a robust, regulatory framework that ensures that clinical research is conducted in a fair and transparent manner, safeguarding the interests of patients while keeping in line with the basic tenets of science. India needs to take a more proactive role in conducting Clinical Research for India. A more conducive regulatory framework for the conduct of clinical research in the country will enable this and encourage local innovation, ensuring that Make in India is a reality for the drug development and clinical research sector in India" stated Ms Thatte.

"However, India should undertake operational research on diseases and should establish good surveillance systems and develop validated data banks which in turn will enable more number of clinical trials/research. The data gaps need to be addressed with high priority given to operational research and adequate resources being allocated," said Dr Devarakonda.

She continued, "The necessity of conducting clinical trials for better therapeutics should be effectively communicated to the public, patients, media, policy makers, more and more participation in clinical trials so that number of these medications could be made available to Indian population not only during clinical trials but also in some cases post trial before even products gets commercialized when proven beneficial with reduced risks."

Future outlook

The future for clinical research in India certainly looks more encouraging today than it did 2-3 years ago. One of our greatest challenges is to instill confidence and trust amongst global stakeholders about the evolving and more scientific regulatory

environment in India and the fact that there is now a more conducive environment for clinical research in the country.

"Few global companies have already started testing the water as definitely India offers a substantial cost advantage relative to developed and emerging economies, the urban healthcare infrastructure in terms of beds/ physicians/ nurses will be comparable with the global average. India offers an abundant and growing pool of skilled, talented and experienced medical professionals, several government-funded pharmaceutical and medical institutions with state-of-the-art facilities, which can serve as ideal centers for multi-centered clinical trials," said Dr Devarakonda.

It is the collective responsibility of all stakeholders across the clinical research to restore confidence in a clinical research process that stands not only for quality and innovation, but also safety and ethics, while also highlighting the need for clinical research in the country.

"We hope that we will eventually reach a state where we are recognized for the high quality of clinical research done in the country, there is more acceptance and realization across the public at large about the role and relevance of clinical research in India and that it contributes to the greater good of everyone, patients are acknowledged for their selfless contribution to bringing new drugs and new treatment to market and we will, in particular, discover new drugs and treatment to treat illnesses that are endemic in our country," said Ms Thatte.

It is the hope of Indian Clinical trial fraternity that new and reformed regulations once amended further will be able to bring back Indian clinical research industry to the highest global ethical standards very soon.

some of the positive developments:

Revamping of Regulatory Review and Approval Process
Governance over Clinical Research Conduct at Sites
Monitoring of Clinical trials
Monitoring of Ethics committees, ethics committees registration, establishment of Subject matter experts committees for review of clinical trial application
Scientific discussion with sponsors before Clinical Trial application so that critical aspects of the study could be discussed and concerns addressed
Limiting the number of trials performed by Principle investigators at the same time
Limiting recruitment of too many patients at one site within a set period of time,
Improved review of clinical trial applications by reducing the timeline to almost 6-7 months
Compensation to only events related to clinical trial drug and audiovisual recording for selected clinical trials