BioSpectrum the business of Bio & Health Sciences ASIA EDITION

India's resurgence as a clinical trial destination

21 September 2016 | News | By Aishwarya Venkatesh

India's resurgence as a clinical trial destination

Singapore: Factors such as technically competent workforce, large genetically diverse population, easy patient availability make India one of the most preferred destination for clinical trials. However the booming clinical trial industry was hit in the past few years due to the uncertain regulatory environment in the country and as a result many foreign companies withdrew their clinical trials from India Fluctuations in regulations over the past few years have reduced the number of clinical trials run on the subcontinent but now governing bodies are looking at new ways to attract trials and prepare a robust regulatory framework for the billion dollar clinical trial industry in India.

In a bid to create a conducive environment that fosters research and new drug development in India, the government has amended some critical clauses and framed new guidelines in line with the global regulations. The latest changes have cheered the industry. Speaking to BioSpectrum Asia Magazine, Ms Suneela Thatte, president, Indian Society for Clinical Research said that, India, now has a very robust regulatory environment which is focused on quality and where patient safety and confidentiality is not compromised.

In an interaction with Ms Suneela Thatte:

Q.India's clinical trials industry has been through a trying phase for the past few years. In your opinion what could be the major reasons.

A. The last few years were extremely challenging for all stakeholders involved in clinical research in India. Various external factors - hasty regulatory reforms, judicial and social activism and some sensational/misleading media reporting- posed a challenge to the conduct of clinical research in the country.
The judicial proceeding of the Supreme Court PIL and social activism resulted in knee-jerk regulatory reforms that had patient wellbeing as an objective but were hastily thought through without any stakeholder consultation and implementation guidance. The hardest hitting was perhaps Rule 122 DAB of the Drugs and Cosmetics Act (released in January, 2013) which

introduced new compensation guidelines that made it untenable for clinical research to be done in the country. Slow approval timelines and other unexpected guidelines that were also introduced in 2013-2014 made the Indian regulatory climate uncertain and unpredictable and acted as another major deterrent for sponsors of clinical research.

Late 2014 and through 2015, however, 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. The compensation guidelines are now more balanced and rational and we are beginning to see more predictable approval timelines with the expansion of the Subject Expert Committees. The revised guidelines rationalized compensation and medical management for injuries caused during and due to participation in clinical research, thereby balancing the interests of the patients and innovators, while at the same time bringing clarity in the process. What was also noteworthy is that for the first time in the world, formulae have been introduced by the Regulators for calculating the financial compensation based on no-fault principle. This not only provides ease of implementation and consistency but also helps the sponsor of the trial to understand the maximum possible liability and plan appropriately while protecting the patient wellbeing. Several other new orders and guidelines have also been introduced which are more inclusive of stakeholder feedback, the most recent being removal of the restrictions on the number of clinical trials an investigator could do at a given point in time and the minimum number of beds a clinical trial site needed to have.

Q.With the ease of regulations, are pharma companies now keen to do more trials in India?

A. I don't think we should refer to the recent changes as an 'ease of regulations' as that gives an impression that the guidelines have been relaxed, leading to erroneous perceptions that patient safety is being compromised. Rather what we have seen is balance brought about in the regulations to ensure that they are more scientific and in line with global regulations and guidelines,while also addressing the unique challenges of our country.

Having said that, yes sponsors of research who include Indian and multinational biopharma companies, not for profit organisations and academic and teaching institutions are certainly looking at India anew. However given what has happened in the last few years, global sponsors need to be reassured of the Government's commitment to ensuring a better climate for clinical research in India. Trust and confidence take time to build but it is an area that needs a lot of focus. Clinical research in our country is a health imperative and important to the progress of the health of our people and the economy. We have the world's largest population and the highest disease burden in the world and yet less than 1.4% global clinical trials are done in India.

Q.Do the new regulations make India a better place to conduct clinical trials?

A. Yes, we certainly have seen a lot of revisions in regulations over the last year and a half and now have a very robust regulatory environment which is focused on quality and where patient safety and confidentiality is not compromised. India has a lot of favourable factors for the conduct of clinical research which include:
-A large and diverse patient population
-GCP trained and skilled investigators
-Good sites and infrastructure
-A regulatory environment committedt to patient centric clinical research.

Better is a relative term but what is important is that the trials being done in India should be significant enough to address our growing burden disease and the unique healthcare requirements of our country. It is only through clinical research that we have found and will be able to find newer and better medicines to treat our population and reduce mortality rates for various diseases, including those unique to our part of the world.

Q.Will these new regulations spur drug development and help encourage R&D?

A.We hope they will. Studies have shown a direct correlation with the amount of clinical research done and innovation in a country. We hope the new regulatory environment will encourage more innovative and path-breaking R&D in our local biopharma companies as also in many of our well established teaching and academic institutions.

Q.In your opinion what are the initiatives needed to build a robust regulatory environment and make India as one of the best destinations for clinical research?

A. We already have a robust regulatory environment and in fact perhaps one of the most regulated in the world. What we now need is investment by the regulators in capacity building and infrastructure to ensure better governance and management of

clinical research in the country. We need quick response to and efficient management of the new guidelines and regulations in particular.

We also need greater awareness to be created globally about the regulatory changes in India and an assurance to be communicated by the regulators of the Indian Government's commitment to a conducive clinical research environment in the country. Building trust and confidence is a slow process but needs to be heavily invested in if we want to reassure global stakeholders about doing clinical research in India.

An important part of this process is also creating awareness amongst the India public about the role and relevance of clinical research and their rights and responsibilities as patients. We believe the media has and can play an important role towards this objective.
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
-we will, in particular, discover new drugs and treatment to treat illnesses that are endemic in our country.

We hope too that more patients and patient advocacy groups will be part of our goal of creating more awareness about the need for and role of clinical research in India.

Q.**Key Trends in Indian clinical trial space.**

A. Some of the trends we have seen as a result of all that has happened in the last few years are:

-Greater collaboration between all stakeholders of clinical research in the country
-Emergence and exponential growth of new services within the larger clinical research realm, including but not limited to data management, pharmacovigilance, remote monitoring, biostatistics, etc. The slowdown in the clinical research industry provided an opportunity for many companies to expand their services into these areas, while leveraging the skilled talent in India for life sciences, analytics and technology
-Innovative indigenous research by Indian companies. The launch of the Rotavirus vaccine is an excellent example of this.