A Regulated India – For Clinical Trials

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A lot has been happening in India recently especially within the government sector. The consequences of course are yet to be seen.

Just before 2011 until 2013 when the DCGI literally grounded to a halt, we all knew that the most awaited changes were definitely coming. And now, when we are finally able to see the changes, it looks very promising. Sponsors are now considering India for their clinical trials and there is a gradual increase in the number of approvals from the regulatory.

The Past

In an environment which predominantly consists of patients below or just above the poverty line, who are illiterate (at least in terms of knowing what clinical trials are) and who do not have access to the best available treatments for their diseases, majority of our patient population for any clinical trials come under the special group.

For a developing country with some of the highest patient population for most of the therapeutic areas, it was a very slow progress when it comes to the changes within the regulatory networks. The obvious loop holes which could be seen especially when it came to patient safety was a let down from the Pharmaceutical industry, regulatory network and ultimately the Ministry of Health.

With The Drugs and Cosmetics Act and Schedule Y in specific to refer to for any local regulatory laws and guidelines, it was beginning to become clear that something more was required to save our patients from becoming guinea pigs in multi-national clinical trials.

When the DCGI, CDSCO and the Indian Government realised the importance of safety when patients were not compensated for their Serious Adverse Events and Deaths, things came to a standstill. Pharma companies and CROs

were scrutinized for explanations and compensation. The practices and processes being followed for approving and overseeing trials were examined and thus the changes were initiated.

The Present

After much reviews, meetings, discussions, analysis, petitioning and planning, the Ministry of Health, DCGI and CDSCO together have now started to roll out improved systems, clearer guidelines and experienced hands to handle clinical trial applications.

Some of the highlights of these changes realised by CDSCO can be found in http://www.raps.org/regulatory-focus/news/2014/07/19675/India-Releases- New-Clinical-Trial-Rules/

OCTAMS (Online Clinical Trial Application and Monitoring System) is the online application system which is a first step towards quick and sophisticated application process. This system is similar to the IRAS (Integrated Research Application System) in the UK which has proved to be a success. OCTAMS is still continuing to an optional process and the paper application is also in use.

A well-illustrated guide for using the online system can be reviewed in http://www.cdsco.nic.in/writereaddata/User-Manual-Online-Clinical-Trial-Application-Monitoring-System.pdf

An average of 21 trials were being approved each month in 2012, which declined to just 6 trials in 2013. There were was a major halt in conducting clinical trials after the Supreme Court order in Sept 2013 and 2014 saw very the lowest approval numbers. However, since Jan 2015 when the new regulations and processes were released, approx. 4 clinical trials have been approved which though not a healthy number is definitely a good start.

The other major hurdle faced by the clinical research industry is the requirement of audio-video consenting process which can prove to be ethically difficult. But the industry has been positive about this new requirement and has implemented it successfully.

The Future

There is still a long journey ahead.

In the ever changing clinical research industry, such major changes will be difficult towards successful implementation. Hence a strong support from the Industry and the clinical research professionals in and around the world is vital.

OCTAMS which is proving to be a worthy portal for successful applications and also due to its transparency and traceable nature, should be widely implemented and put to use more than the paper based application system.

DCGI has already started to focus on increasing their staff count which will ensure a decrease in processing times for any application.

Amendments to the Drugs and Cosmetics Act (1940) at this phase will also be useful and help in improving the standards.

The Government and the authorities are focused and driven to complete this mammoth task.

India is still a strong base due to the genetically diverse patient population, experienced doctors and clinical research professionals and is open to implement any technologically advanced solutions for conducting clinical trials. Hence, India should be approached for conducting clinical trials which will ultimately benefit the introduction of new and improved therapy for various diseases and lead to a healthier nation.