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Speeding up clinical trial timeline only way to deal with India's disease burden

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The Indian Society for Clinical Research (ISCR), an association of clinical research professionals, has announced the appointment of Dr. Chirag Trivedi as its President for the term 2017-19.

Noting his focus at a time when clinical research is coming out of a boisterous few years, Dr. Chirag Trivedi is aiming to bring continuous efforts with the help of the government and regulators so that it improves regulatory environment, develop transparency and shorten clinical trials in India.

- How do you see the future of Indian clinical research?

We have had a lot of changes in the regulation which is making the regulations more robust, transparent and predictable. These changes have helped us to make a more vigorous framework from where we can lead India further for more efficient clinical research. As I said earlier obviously we need to have drugs that will be developed here and for that we will need to be the ready with all statement of the ethic committee, investigators, CROs, Pharma companies the regulators. Everybody should be working together towards this common goal.

- How has the change in norms affected clinical trials in India? Has the scenario improved?

As compared to previous years we have seen a lot of improvement now. Over the last couple of years among the stakeholders we have seen a lot of positive changes now so they have been a lot of clarifications brought in the regulations which will help us to have a robust framework to protect the patience which will ensure quality and at the same time make it easier people to conduct good quality research in India. So over the last few years we have seen quite a few positive changes and these are in the right direction. There are certain areas which we have some space to work on but we have come a long way now and there is a significant progress.

To name a few there are changes in compensations, the way in which compensations was segregated in 2013 so we had to compensate for everything that happened to the patient even if it was not involved in the trial. Now that is much more rational that if it is related you pay for the medical management and if there is an injury due to which the patient had to go through certain things so you compensate over a number.

- With a huge disease burden India needs to innovate new drugs and fight diseases. 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?

As I said earlier, we do have a large disease burden and for sure we need proper clinical research as our patients are suffering and that is where we need to make it easier so the step that have been taken by the government in last 2 years we should continue those reforms. At the same time we should now need to have India at the center of all this. Sometimes it's the global drug develop that happens across the world, India dsnt have the edge in terms of timelines then we may lose out. Its may happen that globally they all move ahead and India may not participate. So there what we need to see if we can cut out the research period to sorter time so that India gets a competitive edge. So then India can be developed as global competitors and our patients will be able to get those drugs faster.

So next thing that can be in the way review process happens there are 3 tiers which define the government if the apex committee has approved it then it will give the final nod. Is it required for all the branch to go through all the levels. So that standardization of the review process and the time lines of it is what need to be worked out.

- What according to You, makes India an attractive destination for clinical trials?

So again to my point on 'large disease burden' we do need new drugs so that itself is one point. As we know patients are calling new medicines so we will need that. With these regulations which are more balanced, robust, predictably in time line that gives India that edge that we count.

- Key Trends in Indian clinical trial space.

As I said there is more advancement in digital space now. Last year GCB the good clinical tactics guidelines they got revised so they also have newer things now. India needs to stand at equal levels now so we are abreast with all the advancements of the world. We have example wherein some people done certain things we need to do it more than before. So all those things have progressed and we need to continue with that. Because tomorrow the world is going to be a different place and India has to be ready for it.

Comments