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“There is also a need to increase awareness about the good that clinical research has done for patients”

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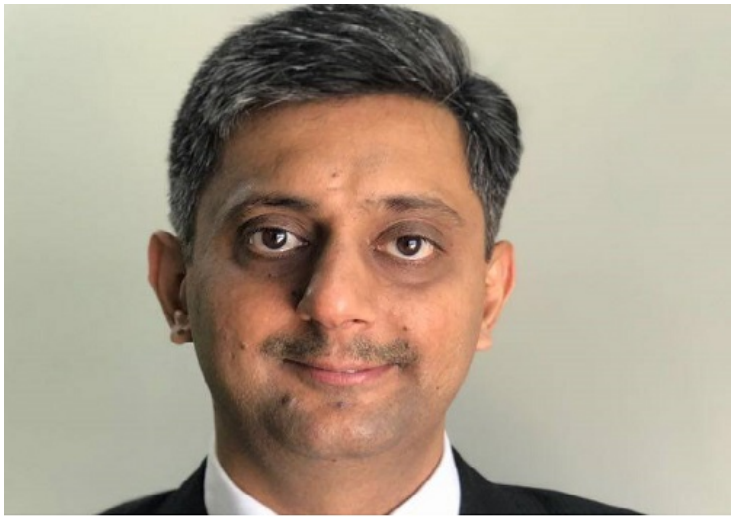

The Indian Society for Clinical Research (ISCR), an association of clinical research professionals, has announced the appointment of Dr Chirag Trivedi as its President for the term 2017-19. Dr Trivedi takes over the reins from Suneela Thatte who was President for two terms from 2013-217. He, who holds a doctorate in Pharmacology and has worked across the biopharma industry for over 14 years, brings rich and varied clinical research experience to his role as President of ISCR. As President, he is responsible for spearheading ISCR’s efforts to build awareness of clinical research as a specialty in India and to facilitate its growth in the country, while helping to evolve the highest standards of quality and ethics. He was earlier the co-chair of the Investigator Council of ISCR. In an interaction with BioSpectrum he has shared his views about the future of clinical research in India. Excerpts of the interview:

- **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 in India and for that we will need to be ready with all statements of the ethic committee, investigators, CROs, Pharma companies and the Regulators. Everybody needs to work 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 there has been a lot of clarifications brought in the regulations which will help us to have a robust framework to protect the patients which will ensure quality and at the same time make it easier for people to conduct good quality research in India. Over the last few years we have seen a quite 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. In 2013 we had to compensate for everything that happened to the patient even if it was not involved in the trial. Now things have changed. If there is an injury due to which the patient had to go through certain medical procedures, then you need to compensate the patients.

- **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. We need proper clinical research as our patients are suffering. We need to make it easier for them to get access to new drugs. For that the steps that have been taken by the government in last two years we should continue with those reforms. At the same time we should now, need to have India at the centre of all this. Sometimes it's the global drug development that happens across the world, India doesn't have an edge in terms of timelines then we may lose out. It may happen that globally the companies may move ahead and India may not participate in trials. What we need to do is if we can reduce the trial timelines so that India gets a competitive edge. Then India can be part of the global trial procedure and our patients will be able to get those drugs faster.

The next thing that can be done is to change the way the review process happens. There are three tiers which the government has defined. If the apex committee has approved it then the government will give its final nod. It is required for the entire review process to go through all the levels. So that standardization of the review process and the timelines of it can be worked out.

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

Again to my point 'large disease burden' is where we do need to focus upon. As we know patients are eagerly to looking for new drugs. These regulations which are more balanced, robust, predictably on timeline will give India an edge over the other countries.

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

As I said there is more advancement in digital space now. Last year we have revised the guidelines for good clinical practices (GCP) for trials. With this developments India is on par with other countries of the world in doing clinical research and trials.

- **How ISCR will play a role in developing the Indian clinical trial space?**

ISCR's continuous advocacy efforts with the government and regulators has contributed to an improved regulatory environment, increased transparency, more clarity of processes and a shortening of clinical trial approval timelines. Given the huge disease burden India carries, it is crucial for us to scale-up clinical research as that will be the solution to many of our public health challenges. We will continue to focus our efforts on engaging with new developments that will impact the sector, including the revision of the Drugs & Cosmetics Act and the accreditation process for Ethics Committees. There is also a need to increase awareness about the good that clinical research has done for patients by engaging with key stakeholders and strengthening ISCR's position as a value adding knowledge partner.

Anjali Jha