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No clinical trials equals no new drugs: ISCR prez

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Q: What is the current status of clinical research in the country now?
Ms Suneela Thatte: Currently clinical research is hit by two primary reasons. Firstly, it is the clinical research review and approval timelines, which are very unpredictable.

The waiting period is making India a more unattractive destination for clinical research organizations (CROs), and as well as for academicians to carry out clinical trials in the country.

Secondly, the compensation guidelines have totally tilted the balance, and there is a massive misuse potential factor to it. This is driving a lot of organizations away.

This is not just affecting industrial research but also academics. Usually academic researches operate on tight budgets. The current guidelines require that an average compensation payment be between Rs 35-45 lakh. This amount could be the actual proposed budget for the entire clinical trials.

As a result, investigators are scared to do clinical trials, patients are doubtful about participating, and sponsors hesitate to

conduct trials in India.

This applies both to Indian pharma companies and MNCs. Thus India's research innovation is going to other countries. It is excruciatingly sad to see that we can't do anything for the healthcare needs of our own country.

Q: What are the negative trends that you see in the CRO business?
A: The number of trials is going down. We need trials because we have unmet medical needs that are different from China or the US or other European countries. Our unmet needs are addressed by our local pharma industry.

We also have affordability issues. We are moving from chemical to biological medicines, and then towards personalized medicines. However, biologicals are very expensive. But biosimilars are a solution towards making affordable medicines.

Many Indian innovative pharma companies are very bullish about their biosimilars development. However, owing to the current laws, the clinical research is hampered.

When clinical research happens, patients have early access to a medical breakthrough. As the number of clinical trials has gone down, today that advantage has been taken away from patients.

Q: What is ISCR doing under these challenging circumstances?
A: Our approach is that, we are continuing our advocacy with regulators. We are trying to bring attention on why we need clinical research. No clinical research means no new drugs. That's the simple equation.

We are working with the regulators as to how the regulations can be balanced, and simplify implementations that can be followed. We are doing this in partnership with investigators, ethics committee members and patients.

Ultimately, patients need to come forward and say that clinical research has certain risks and that it may or may not benefit certain people.

Q. How is the business model transitioning?
A: From the industry and skill development perspective, a lot of clinical research professionals have to look at alternate career options, which is not as equally exciting as being a part of live clinical research.

If clinical trials would have grown as predicted in the past, we would have had tremendous employment opportunities for medical and lifescience graduates. Sadly, that has not become a reality.

Q: How are Indian companies and MNCs responding to this?
A: There is a wait-and-watch approach between MNCs and Indian pharma companies. Unfortunately, India now is not a country of choice for both of them.

But the good thing is nobody has totally given up hope because India has a very good ecosystem for clinical research in terms of ethics committees or investigators.

So everybody now is trying to reach out to the regulatory authorities to see how the regulations can be balanced.

Q: Overall, how is the clinical trials climate in the APAC region?
A: With India's exception, all the other countries in APAC are trying to facilitate clinical trials. Countries like Sri Lanka has tremendously benefited because of India's slowdown.

If you look at other APAC countries, not just from the clinical research perspective but also from the innovation point of view, they are promoting innovation in every possible way like tax holidays, and offering SEZs to conduct businesses with ease.

Every country has a vision for innovation which India hasn't realized because of the policy paralysis. Hopefully, now we have seen some changes with the new government in the center.

Q: Which are the APAC countries that are leading in clinical trials?
A: Malaysia, Singapore, China, Taiwan, and Korea are doing extremely well in supporting innovation. We are way behind Taiwan and Korea in terms of clinical trials.

Q: Are you seeing new CROs cropping up in India despite the dilemma?
A: Many clinical research companies are not public. So we don't have new entrants at this stage. But many CROs are re-skilling and are looking at other support businesses like data management and data processing.

These are the areas where they are diversifying, so that their employees have alternate options.

Q: What is the status of the recommendations laid out by Prof. Ranjit Roy Chaudhury expert committee?
A: Quite a few of them have now been acknowledged by the way of office orders, whereby the intent to implement them has been published by the government. Now what is important to see is the implementation roadmap.

Q: What is the proposed solution for overcoming these challenges?
A: The only proposed solution in my view is the stakeholder consultation. The regulators must hear from all the stakeholders and balance the regulations.

Again, policy stringency is necessary, and regulations have to be robust, but they need to be predictable and balanced. This will only happen through stakeholders' consultation.

Clinical research should not be looked at as a separate specialty. We should look at it as a part of the healthcare agenda of our country. That is the approach we have to take and then solve issues that are unique to our own country in terms of lack of healthcare access.