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'Now, India has a balanced, scientific regulatory framework for clinical trials'

06 June 2017 | Opinion

"With only 1.4% of global clinical trials in a country that has the highest disease burden in the world, we need to encourage more sponsors to conduct clinical research in India as well as create a strong eco system for indigenous innovation and R&D," says Naz Haji, SVP & Managing Director, QuintilesIMS India during an interaction with BioSpectrum Asia Magazine. Please check below for excerpts

With new regulations in place India is gaining traction in the clinical trial space again. Your thoughts on this?

There have been a lot of positive developments in the clinical research regulatory environment in India in the last couple of years and we now have a regulatory framework that is more balanced, scientific and focused on patient safety and ethics. While sponsors are beginning to re-evaluate earlier decisions to move studies away from India, we will see the real impact of these changes in 2018. This is because not only is the clinical research decision process long, but regaining the confidence and trust of global stakeholders in doing clinical research in India will take time. It is the collective responsibility of the entire clinical research fraternity and it is important that we all stay connected and together on this journey with a focus to ensure safer and better outcomes for patients.

In your opinion, what are the biggest challenges clinical research organizations in India face today?

As I said earlier, given the unpredictability of the clinical research regulatory environment a few years ago, there is an important need to rebuild confidence and trust in doing clinical research in India. Global sponsors need to be made aware of the recent regulatory changes and the commitment of the Government and regulators to creating a safe and secure environment for clinical research in the country. They need to know how these changes are contributing to safeguarding patients, bringing more predictability in the regulatory environment and reducing approval timelines. The other big challenge

before us is to make sure that global sponsors are aware of the high quality of clinical research being done in India. We cannot allow instances of data integrity and similar findings that have impacted the biopharma industry to tarnish the image of the clinical research industry in the country. With only 1.4% of global clinical trials in a country that has the highest disease burden in the world, we need to encourage more sponsors to conduct clinical research in India as well as create a strong eco system for indigenous innovation and R&D.

For many years now, QuintilesIMS has been among the best CRO's in the region. What according to You is helping QuintilesIMS sail successfully through the challenges in India?

For one, I believe it is our legacy, reputation and partnerships. From a CRO perspective, we conduct business in approximately 100 countries around the world. The majority of the clinical studies we conduct are performed across multiple countries and continents using the same protocols and patient protections. Because these global studies generate data that is ultimately submitted to multiple regulatory agencies around the globe,we conducts clinical trials to the same high standards around the world. Regardless of country, we strictly adhere to universally accepted ethical principles articulated by international and local guidelines and these are supplemented by our own policies and procedures. We have worked directly and in collaboration with the regulators and other key stakeholders in the country to address the challenges of the last few years and build a regulatory environment that is more balanced and patient-centric. The other is that we have a well rounded portfolio of services. Our Indian workforce has been a key contributor to the way in which QuintilesIMS supports both our global and local customers and our headcount in India has been growing over the last few years. Given the highly skilled talent, technological capabilities and experience available in India, we are uniquely positioned to emerge as a leading destination in the delivery of these services to global companies. We have a balanced portfolio of clinical services which include biostatistics, data management, cardiac safety services, pharmacovigilance and IT services besides core clinical trials, and have had a strong presence in these areas for several years now. With the QuintilesIMS merger in 2016, we are now a leading integrated information and technology-enabled healthcare service provider worldwide and now provide solutions that span clinical to commercial.

Which countries in Asia are doing well in the outsourcing space and why? What are the current trends in the Asian CRO industry?

Biopharma outsourcing is growing across Asia, as local and multinational companies recognize the benefits – variable vs. fixed costs, cost-efficient access to expertise and infrastructure, risk management, partnering vs. going it alone, to name a few. In its 2016 Report, Asia: Preferred Destination For Clinical Trials, Frost & Sullivan cited Asia's 4.4 billion people, most treatment-naive; skilled investigators; robust clinical infrastructure; faster patient recruitment and lower costs relative to the West; and high-quality output as factors behind the CRO industry's growth. At the country level, it's a complex story. China and India have the greatest potential because of their size (world's No. 1 and 2 largest countries by population). China's biopharma industry has grown rapidly, as has outsourcing, over the past 10+ years, driven by both MNCs and local companies. Growth in India has lagged because of regulatory issues but that's beginning to change because of regulatory reform; we believe India is poised for growth as a result. Taiwan and South Korea have strong clinical research infrastructures and a growing number of local companies looking to expand globally. They have been and continue to be bright spots for outsourcing. Japan and Australia-New Zealand represent the region's mature markets. Japan is an important market for CROs because of its size. Finally, South East Asia has great potential because of its large population and potential for rapid recruitment and lower costs.

What is your message for International Clinical Trials Day?

I would like to begin by acknowledging every single stakeholder of clinical research for their contribution to drug development, especially patients who through their participation in clinical trials have contributed to new drug discovery and treatment. International Clinical Trials Day is an important time for us to look ahead at what we need to do to encourage more drug development and innovation in India. It is a time for all of us to renew our pledge to quality, ethics and patient safety.