“Need to educate the general public about clinical research”

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By : BioVoice News Desk - December 1, 2016

While he joined his current role in 2015, Mr Naz Haji has been a part of QuintilesIMS since 2006 as Vice President, Global IT, leading its global infrastructure and operations. In a chat with the BioVoice, Naz shared insights into his organization’s activities in India besides

opinion on clinical research scenario in India. Read his detailed interview with Rahul Koul below:

Please take our readers through the major initiatives at QuintilesIMS India since you took over the mantle a year ago?

I took over the India CRO business at a very critical inflexion point for the clinical research industry in India. After a challenging couple of years when clinical research in the country was impacted by an unpredictable and uncertain regulatory environment, we had in late 2014-2015 begun to see revisions in some of the earlier contentious guidelines and orders, as well as new regulation that was more rational and indicative of stakeholder feedback.

My major focus was working closely with my Clinical Operations team to ensure that we were in a state of preparedness to take on the requirements of a 'renewed' regulatory environment and the business that was likely to come to India as a result. This included new systems and processes to incorporate the revised regulations and new ways of working. My job also involved working with global colleagues to make them more aware of the regulatory changes in the country and what this means for doing clinical research in the country. It was also to provide strategic support and counsel to our customers and helping them navigate through the changing regulatory environment. My agenda also included ensuring that we continued to work with a single minded focus on patients.

What kind of strategic alliances has the company forged in recent years and the respective objectives?

There are many alliances that QuintilesIMS (previously Quintiles) has announced in the last three years. One is the merger of IMS Holdings with Quintiles pursuant to which the companies have combined in an all-stock merger of equals transaction. The merged company has been named Quintiles IMS Holdings, Inc. The strategic rationale is to combine IMS Health's rich, global information solutions with Quintiles' industry-leading product development skills.

QuintilesIMS also joined hands with Quest Diagnostics to launch Q2 Solutions, a new combined clinical trials laboratory services organization. Q2 Solutions has brought together the clinical trials laboratory operations of the two parent organizations to provide biopharmaceutical customers with the diverse capabilities and end-to-end services required in the rapidly evolving biopharmaceutical industry.

The company also did acquisition of Novella Clinical (Novella), a full-service clinical research organization (CRO) focused primarily on emerging oncology customers as well as those in the medical device and diagnostics sectors. By joining QuintilesIMS, Novella will be able to continue this specialized focus while at the same time leveraging company's scale and resources to provide new

global capabilities to its existing and future customers.

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Given the fact that the CRO industry has not been doing that well in last few years, has it really affected the company?

We believe the industry backdrop for the CRO industry continues to be strong globally, as evidenced by our growth over the past several years.

Our Indian workforce is 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 services, primarily in the product development space, 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. We are seeing growth in these services driven by a demand for customers to seek solutions from an organization that has a winning combination of global healthcare expertise and a strong technology base.

How do you view the growth opportunities in Indian market? What are your immediate priorities for the company?

As I mentioned earlier, one of my priorities is to work in collaboration with other stakeholders to create greater awareness globally about the changes in the Indian clinical research regulatory environment. Sponsors are beginning to re-evaluate earlier decisions to move studies away from India but restoring confidence and trust takes time. All stakeholders have an important role to play in rebuilding this trust given the high burden of disease we have in the country and the need for more investment in clinical research.

Another focus for us is the domestic customer segment. We have been working very closely with Indian biopharma companies to support their growing global aspirations. With our extensive regulatory and biologic development experience and special offerings in generics and biosimilars, we are well positioned to help domestic players navigate the complexities of drug development and

commercialization in different markets.

With recent regulatory developments in the Medical Devices segment in India and the offering we have in this segment through our acquisition of Novella Clinical, this is another area of focus.

> **“Perceptions about clinical research in the country have been impacted by the developments of the last few years. There is a need to educate the general public about clinical research and about their rights and responsibilities of patients.”**

Do you find the regulatory set up in India satisfactory? What are the challenges before CRO industry?

Yes, a lot has evolved over the last year and a half which has led to improvements in approval timelines and a more robust and transparent regulatory system. What has been equally encouraging as we rebuild the clinical research environment in the country is the collaborative approach by the regulators with stakeholders, be they from the industry, investigator or patient community, advocacy groups or not for profit organisations.

However, there are still areas to be addressed.

We now need to ensure that the commitment and resolve of the regulators to bring clinical research back on track in India is supported by strong governance and infrastructure to ensure this happens. With the number and pace of change in the regulatory environment, additional regulatory infrastructure is needed to ensure compliance with the new regulations.

What is also a critical requirement is a larger ecosystem that recognises the role and relevance of clinical research in India. Perceptions about clinical research in the country have been impacted by the developments of the last few years. There is a need to educate the general public about clinical research and about their rights and responsibilities of patients.

We hope these areas will be addressed soon enough and that we do not see a repeat of the challenges we faced in the past couple of years.

What is your business and financial outlook of QuintilesIMS India for the next one year?

We do not make speculative comments. QuintilesIMS India is and will continue to play a strategic

role in QuintilesIMS’ growth.