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"Maturity & quality of Indian clinical trial ecosystem has been very well demonstrated"

Ajay Tandon, Managing Director, Veeda Clinical Research Limited provides an overview of the trends, market scenario and way forward

By Rahul Koul

Can we say with confidence that the CRO industry is heading back to its golden days again? What has changed in the last few years?

India continues to have the attributes that should progressively enhance the scale of clinical trials in the country to support the global development of novel medicines and therapies. We have a large population with a correspondingly high disease burden that provides a significant pharmaceutical consumption market. This should motivate the sponsors, to include India in global clinical trials for prospective medicines and therapies.

Many key aspects have changed significantly over the recent years, and is reflecting in the growth in global clinical trials that include India. The New Drugs and Clinical Trial Rules of 2019 have provided clarity on key concern areas such as regulatory approval processes and timelines; ethics committee operations and oversight responsibilities; and sponsor compensation liabilities in case of Serious Adverse Events observed in the trial participants. Moreover, there is continuing focus by the regulator to streamline systems and procedures to facilitate clinical trials with data integrity and quality aligned with global standards.

The network and quality of investigator sites have evolved quite significantly with well trained and equipped trial professionals and infrastructure conducting trials in compliance

with ICH GCP standards and successfully qualifying under global regulatory inspections. The network has been developed by an increasing base of high quality Indian CROs in collaboration with the major pharmaceutical companies operating in India.

The increased agility, maturity and quality of the entire Indian clinical trial ecosystem has been very well demonstrated through the successful and rapid conduct of large scale COVID related clinical trials that were globally accepted. The ecosystem is continuing to expand and develop further which should underline continuing relevance and participation of India in global clinical trials.

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How can we accelerate the expansion of clinical trial sites in India?

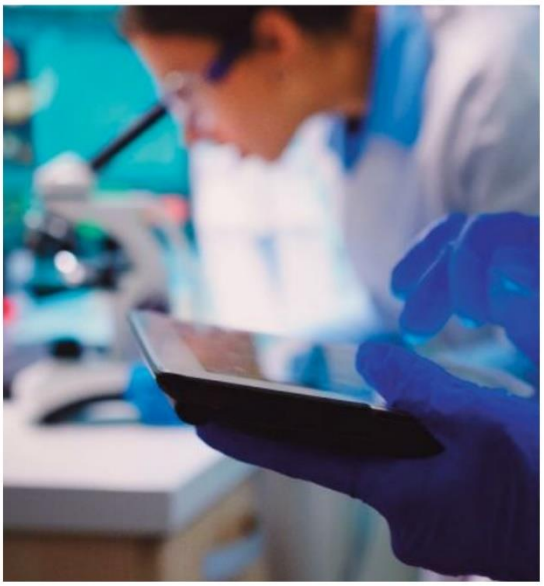
With the expected growth in clinical trials in India, there is certainly the need for the operating network to supportively expand to ensure that trial participation and benefit is continuously broad based. It is important to ensure that the intensity of trials at sites is well balanced to allow for necessary attention and quality of outcomes; and the cost of trials does not inflate unduly under competitive intensity.

However, there will be a concerted effort required by the multiple stakeholders - clinical trial sponsors, CROs, public and private sector healthcare service providers, insurers, industry associations such as ISCR, government healthcare and research agencies and the regulator - to ensure that the network of investigator sites and the professional talent pool is rapidly developed through an enabling ecosystem to meet the growth imperative beyond just the Tier 1 and Tier 2 locations. The advancement in the deployment of technology solutions for enabling trial access, patient centricity, data management, risk based compliance management and speed of execution will be a key contributor in this growth objective.

What are the top 5 challenges before the CROs in India?

Some of the key developmental aspects that the Indian clinical trial ecosystem needs to address are:-

- Regulatory enablement of approval timelines, consultative procedures, data requirements and patient access to trials in alignment with global best practices;
- Expanding, both quantitatively and qualitatively, the operating base for clinical



trials, as discussed earlier; Enhancing patient awareness about clinical trials and enabling greater access to relevant clinical trials while ensuring requisite oversight to protect the right, safety and wellbeing of the trial participants. This will also enable sharper feasibility assessments and patient retention through the trial conduct.

• Establishing partnership networks with CROs globally to increase the awareness about Indian clinical trial capabilities and bringing more clinical trials to Indian patients; and

• Cross leveraging and converging the deeper medical, scientific and technical expertise that sits in different industry, academic and public institutions, with enabling regulatory support, to position India at the front end of clinical development and not just as a participating country for selective clinical trials.

• CROs have a key enabling role to drive the development of the industry and should be supported to make the necessary efforts and investments for these. Moreover, they also have a key influencing role in the inclusion of India into clinical trials ab initio as against a contingency rescue plan and the above developments would give them the confidence to do so.

What are the untapped opportunities that will drive its future growth?

While the various initiatives outlined above will facilitate in bringing a significantly greater proportion of global clinical trials to India, the biggest fillip to patient treatment and care will come from greater innovation emanating from within the Indian pharmaceutical and biopharmaceutical industry itself. This will, in turn, boost the scale of clinical development and trials required to be conducted in the country to support innovation.

There is an under tapped potential of the industry – academia – government to collaborate in building requisite capabilities and capacities to support innovation in the country, especially in new age biopharma and biotech. Again, CROs have a key role to play, both as industry participants as well as collaborators with academic and government institutions, to drive this development and leverage the benefits from each other. ■