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The growing focus on GCCs and future of Indiaâ??s CRO market

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Dr Vinod Mattoo, Executive Director, DiagnoSearch Life Sciences, in an exclusive interaction with BioSpectrum India, shared insights into the current state of the Contract Research Organisation (CRO) market in India, its future potential, and the challenges faced by the sector.

What kind of policy reforms are you looking at to revolutionise the CRO sector?

I believe the most meaningful reform would be to make the approval process for clinical research more predictable. Over the last several years, we have made significant progress in harmonising our processes with those followed in other countries. Some distance has been covered, but more still needs to be done. Global research ecosystem demands is predictive timeframe over uncertainty and surprises. Most global companies conduct multinational studies, and once trials begin in other countries, they cannot wait indefinitely. It is heartening to see progress towards a more defined and clear approval timelines, transparent tracking, harmonization with ICH-GCP and global standards; and digital submission (SUGAM) and monitoring systems.

The other low-hanging fruit is institutionalising pre-submission consultative meetings with regulators. This can provide clear guidance on what the regulatory expectations are and will be key to help transparency and reduce uncertainty. With the incentives provided under the framework of Biopharma Shakti Mission, more Indian entities will be inclined to develop drugs, vaccines and devices, and such pre-submission guidance meetings will be very helpful.

Who are your major clienteles in India in the CRO space?

We work with both multinational and Indian companies. As a full service CRO, we are natural extension for pharmaceutical companies in conducting all phases of clinical trials in India and Globally. Our clinical research supports companies that are introducing new drugs, exploring new indications for existing drugs, or conducting similar trials for approved molecules.

We have worked with 13 of the top 20 global pharma companies, as well as Indian Global Pharmaceutical and vaccine companies. In addition, we collaborate with NGOs, academic institutions as well as individual investigators in what is known as investigator-initiated studies. Overall, we have a very diverse client base.

What is the current scenario of the CRO market in India?

The market size is not easily quantifiable. However, a reasonable estimate places it at around $2 billion at present, though this could vary. The market is growing at approximately 9–10 per cent annually, and as a country, we expect it to reach around $5–6 billion over the next 10 years.

What are the current challenges faced by the market?

The primary challenge is the predictability of regulatory timelines. The second challenge is making India commercially attractive, as multinational companies invest in clinical research in countries where they see strong commercial potential. As

India becomes more attractive commercially, we expect greater investments in clinical research. We seem to be on the right path, but I hope this momentum accelerates further.

Another completely untapped area is early phase research where the regulators have been very mindful about allowing first-in-human studies in India. We need to create an eco-system of world class Phase I units and industry friendly regulatory framework taking into account adequate safeguards for patient protection. Initiation of early phase studies could act as a catalyst to exponential growth in late phase studies

Your outlook for the CRO market by 2047?

At this time, it is not an easy to make a reasonably accurate estimate. However, I would expect the market to continue growing at around 9–10 per cent in the near term. However, this is a very rough estimate, given the many uncertainties involved.

How is innovation enabling India's life sciences R&D ecosystem in terms of talent, infrastructure, and collaboration?

Innovation requires skilled talent, robust infrastructure, and the ability to collaborate effectively across geographies. There is currently a strong focus on multinational companies setting up global capability centres (GCCs) in India, reflecting the availability and recognition of the country's talent pool.

For example, several companies have innovation centres in cities such as Bengaluru and Hyderabad. However, moving forward, the key question remains whether we are producing scientists and other clinical research professionals at a rate that matches industry demand.

This talent crunch is already visible, with highly skilled professionals becoming increasingly difficult to find. There is a need for more academic institutions, training centres and extensive collaboration networks with foreign universities.

While India has several training centres and a growing number of B. Pharm graduates, formal research training remains limited. Increasing the number of clinical studies and strengthening the clinical research ecosystem would provide hands-on learning opportunities.

It is a classic chicken-and-egg situation. Directionally, we are moving well, and the influx of GCCs is encouraging. However, a key unanswered question remains: are GCCs merely supporting global innovation from the back end, or will true innovation happen in India itself?

Sanjiv Das
sanjiv.das@mmactiv.com