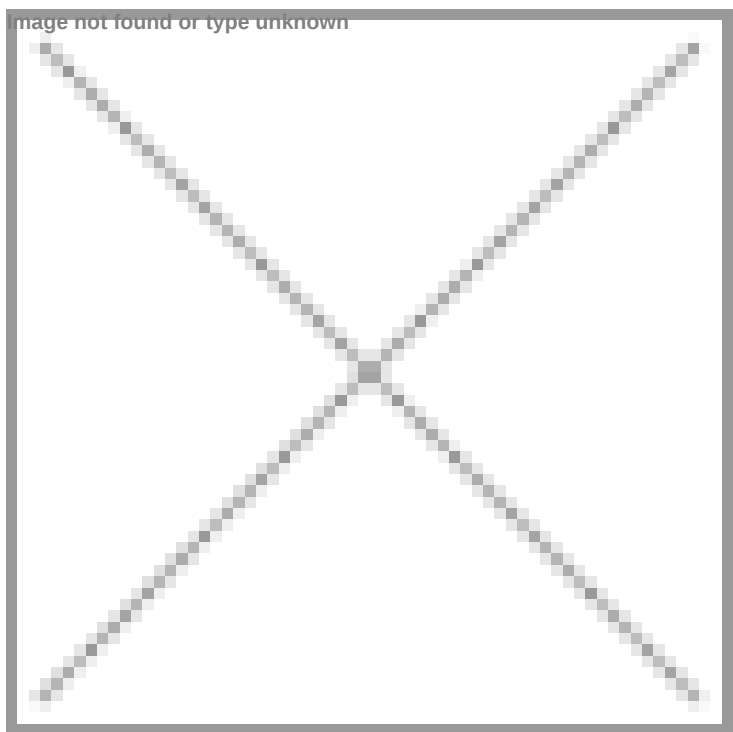


“India enjoys a far greater degree of confidence in IP security for Western partners than does China”

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In a rapidly evolving pharmaceutical landscape, India-headquartered CRDMO Syngene is at the forefront of redefining early and late phase clinical development through precision sciences, AI-enabled analytics, and translational insights, accelerating first-in-human trials and enabling faster delivery of promising therapies to patients. In a recent conversation with BioSpectrum, Dr Kenneth Barr, Senior Vice President – Research Services at Syngene International, discusses the company’s recent transformation of its Clinical Development services into a more strategic, data-driven offering- Translational and Clinical Research (T&CR).



What were the key drivers behind Syngene's transition from the Clinical Development department to a more integrated Translational and Clinical Research (T&CR) model?

One of the key drivers has essentially been the evolving drug development landscape, globally, encompassing the large innovator companies, small to mid-size biotech companies, as well as generics. The cost of bringing a new drug to market has soared, with estimates crossing \$2.6 billion and timelines stretching over 10 years. As a result, there is a growing requirement to improve clinical success rates while compressing timelines and controlling costs. Translational science provides a way to bridge the "lab-to-clinic," or "bench-to-bedside" capabilities by generating data that improves predictability and reduces uncertainty. As drug development becomes more complex, with new modalities, rare diseases, and targeted therapies, integrating translational insights has become essential vis-à-vis a good-to-have strategy.

How does the integration of translational and clinical research within Syngene's end-to-end R&D platform enable the company to deliver differentiated value and unlock new opportunities for clients?

Since success rates in drug discovery continue to remain low, particularly in the early clinical stages, de-risking is no longer optional but a strategic imperative. Translational science bridges the gap between preclinical discovery and clinical development by generating data predictive of clinical outcomes, including immunogenicity, reducing late-stage attrition, optimising candidate selection, and thereby accelerating decision-making. Globally, clients are looking for partners who can provide integrated translational insights that can accelerate patient-focused therapies to the market more quickly, and that is where Syngene can provide a true value-add to its clientele.

What is Syngene's long-term vision for its Translational and Clinical Research (T&CR) offering, and what key milestones are you aiming to achieve as the function evolves?

We envision Syngene as a partner of choice for global pharma companies seeking science-led, end-to-end translational support. With our T&CR division, we are building a fully integrated ecosystem that doesn't just check regulatory boxes but also empowers clients to make better, faster decisions.

We believe the next frontier lies in precision translational strategies, including using multi-omics data, artificial intelligence (AI) /machine learning, and patient-centric design to optimize every step from discovery to clinic. Our mission is to be at the forefront of this transformation, leading the way in delivering smarter and faster solutions.

Beyond the 'India advantage' and cost efficiency, how does Syngene measure and demonstrate agility and speed in clinical trial execution, such as study start-up timelines, compared to industry benchmarks?

While India still offers opportunities for cost arbitrage, India and Syngene are today much more about being a partner in innovation and meeting global standards for scientific excellence. Having a global footprint with existing partnerships spanning across US, Europe and South East Asia helps in a faster trial start-up, patient recruitment, and the overall timelines for a global trial execution. Our clients look to Syngene as a company with a long track record of success, scale, and depth of capability: that is the intellectual arbitrage.

In a competitive CRO landscape, how does Syngene differentiate itself from other mid-sized players in India offering similar translational and clinical research services?

Traditional CROs often operate in specific areas – one may have capabilities in discovery, and other may be a specialist in clinical development. We at Syngene have integrated these to provide end-to-end services. We bring together scientists, clinicians, and regulatory experts under one integrated translational umbrella. Our approach is highly collaborative and science-first, with substantial crosstalk between discovery biologists, toxicologists, DMPK experts, and clinical strategists. This ensures that the clinical programs are outcomes of rational design and translational insight.

What emerging global trends are reshaping clinical research, and how is India positioned to benefit, particularly in the context of China+1 strategies?

In the speed-quality-cost triangle, no client is willing to sacrifice quality. Therefore, the remaining parameters are speed and cost. India is highly competitive in these areas and at present the most significant option for highly skilled CRO/CDMO services in a cost-competitive region.

In today's environment, India enjoys a far greater degree of confidence in intellectual property (IP) security for Western partners than does China. Geopolitical uncertainties, including risks associated with the proposed US Biosecure Act and the ongoing threat of Chinese aggression against Taiwan, we foresee increased incentives for supply chain diversity.

Are you witnessing an increased interest in conducting global trials in India?

Definitely yes, and the credit also goes to the government of India and the Central drug regulatory agencies who have introduced new guidelines (NDCT rules 2019) with a more streamlined, transparent & faster approval processes which has encouraged more global companies to conduct their research in India.

Availability of a large treatment naive patient pool, vastly improved hospital infrastructure, investigators well versed with GCP guidelines, ethics committee oversight, automated data collection platforms, faster approvals, etc., are some of the factors which have also aided to a very large extent in the renewed interest in India as a focal hub for large global clinical trials.

What are your views on the new opportunities & challenges being lined up for the India pharma companies post-patent expiry of many global drugs, such as obesity, diabetes etc.?

The overwhelming percentage of patients globally rely upon cost-effective, generic medications. India has evolved significantly in the prior decades as the leading global supplier in this critical marketplace.

Secondly, patent cliffs & troughs have always aided in bringing in newer frontiers and challenges not just to pharma companies but also to the CRO/CDMO sector in India. Such challenges help bring in newer drug development methodologies, execution modalities & innovation. These are not just limited to the current GLP-1 antagonists that are due for expiry but also to many other biologics & biosimilars drugs related to oncology and metabolic drugs. We anticipate a spurt in difficulty to make biologic entities and more complex drug-development portfolios emerge which invariably helps and also in parallel challenges the CRO/CDMO sector to constantly improvise and innovate.

Additionally, the next frontier for India is to establish a significant, credible innovation ecosystem in which therapeutics discovery can flourish. As India's largest CRO/CDMO, we look forward to supporting this nascent yet growing ecosystem.