Indian CROs: Leveraging digitalization to drive efficiency

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The Asia-Pacific region is experiencing rapid growth in the global drug discovery market, with India currently ranking third globally in pharmaceutical production by volume. Indian pharmaceutical exports reached US$ 25 billion in 2023, and Indian CROs are becoming key players in global partnerships.

The India CRO market was valued at US$ 0.69 billion in 2023 and is projected to continue growing at an annual rate of more than seven per cent over the next few years. Key drivers of this steady growth include an increasing demand for pharmaceuticals due to a rising global population, and globalization of clinical and pre-clinical drug development, combined with increasing digitalization to improve the efficiency of data collection, regulatory compliance, logistics, and supply management. India meets these needs by supplying a highly qualified skilled workforce, and R&D infrastructure with cost benefits.

To support this growing activity, CROs are increasingly forming long-term strategic collaborations with pharmaceutical companies. These partnerships are driven either by pharmaceutical companies outsourcing their R&D to CROs, or by the CROs developing innovative technologies and approaching pharmaceutical companies.

Key drivers for CRO efficiency in drug discovery

In the fiercely competitive commercial environment, CROs are highly motivated to improve production and process efficiency. Streamlined processes naturally enable more resources to be directed to innovation. Efficient workflows also help improve operational scalability and flexibility, enabling a CRO to manage fluctuating demands. While ensuring tight cost control helps to compete in the marketplace, at the same time CROs must maintain very high research standards.

Part of the solution lies with the increasing use of technologies that will enable enhanced collaboration, efficient data-exchange, compliance and security for intellectual property. Many of these, such as automation and big data analytics, are now used as standard, and the newest AI and ML solutions are being deployed – all of which can reduce research timelines and improve client satisfaction.

Leveraging technology to optimize CRO operations

Critically, successful collaboration between a CRO and a pharmaceutical company depends on robust security for data. Working to agreed standards on a shared platform helps to enable the free-flow of communications that is essential for trusted partnerships. Modern solutions using web technologies are designed to be flexible and scalable, with built-in masking of proprietary codes, properties, and material IDs. Adopting a rigorous approach to data exchange that avoids insecure manual processes such as email and spreadsheets helps to safeguard client data and intellectual property, building trust between the CROs and their partners.

Similarly, the implementation of a digital project management system enables CROs to streamline communications, milestone tracking, and workflow optimization. Electronic notebook (ELN) solutions, for example, are increasingly being used as a powerful tool to help research teams work more productively in an environment where the speed and accuracy of data analysis offers competitive advantage.

An integrated approach to these needs can be provided by a unified platform that supports collaboration, secure data exchange with intellectual property protection and data masking, and project management, all within a single technology solution.

Aligning with regulatory compliance

With many new techniques and modalities coming rapidly to market, the pharmaceutical industry is facing additional regulatory complexity, with strict requirements for drug development and clinical trial conduct.

As CROs provide essential support in navigating the complexities of drug development, it is increasingly vital to ensure robust processes that conform with regulators' demands, from biosafety to data security. A full-service CRO in India needs to possess comprehensive knowledge of the intricacies of both Indian and global requirements, ensuring meticulous preparation of submissions and compliance with regulatory standards.

For example, the Cybersecurity Framework global security guidelines, published by the National Institute of Standards and Technology (NIST) in the US, are frequently revised and updated. Similarly, the System and Organization Controls guidelines, more commonly known as SOC2 published by the American Institute of Certified Public Accountants (AICPA), are effectively used a global security standard. In a complex, interconnected world, the only realistic approach to maintain currency with regulations is to deploy automated systems that are always up-to-date, an approach which will help to build trust with partner organizations.

Success stories of CRO collaboration

As an example of a pharmaceutical and CRO partnership, SK Life Science Labs leveraged Signals Notebook, the unified SaaS informatics platform from Revvity Signals to collaborate with more than 40 CROs. With Signals Notebook in place, SK Life Science Labs provided controlled access to secure workspaces that enabled the CROs to record experimental data, allowing in-house chemists to check the CROs' work in real time. SK Life Science Labs found that integrating this technology significantly streamlined partner relationships while increasing traceability, improving inventory management, and boosting productivity.

Similarly, Nimbus Therapeutics, a pharmaceutical company that specializes in small molecules discovery, employs a distributed research model that leverages a network of strategic CRO partnerships to accelerate drug discovery. Working with Workflow Informatics, Nimbus Therapeutics deployed Spotfire from Revvity Signals to provide data visualization that highlighted process bottlenecks. Armed with clear identification of the issues, Nimbus Therapeutics optimized its research model and accelerated drug discovery by cutting the typical data upload time to just 2 days, reducing manual data interventions by half, and increasing screening throughput by 50%.

Future outlook for CROs in India

Technology and global collaboration are reshaping the role of CROs in drug discovery. Since the early 1980s, CROs have expanded from preclinical testing to areas such as clinical trials, data management, pharmacovigilance and logistics.

Remaining competitive in this very active Indian growth market depends on continuous process innovation and proactive client engagement. CROs capable of leveraging AI and machine learning to support virtual screening, lead optimization, and identification of novel drug candidates will be at the forefront of drug discovery in terms of efficiency and productivity. In addition, the ability to screen large compound libraries quickly and cost-effectively through automation, and the capacity to analyze and interpret complex datasets, will help CROs develop high-value-added services such as target identification, lead optimization, and candidate development.

Conclusion

CROs are a substantial growth market in India, providing a vital service to global pharmaceutical companies. To maintain their edge, CROs must continue to grow their technological capabilities, increasing efficiency, improving regulatory compliance, and enhancing data security through the strategic use of new technologies such as fully digitalized informatics platforms. CROs that can offer these benefits will be at the vanguard of the drug discovery collaborations of the future. ◆

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Global pharma eyes India for human studies

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India, with its vast and diverse patient population, presents an ideal environment for these trials, enabling the generation of robust and diverse data essential for scientific advancements.

Conducting clinical trials in India often proves to be cost-effective, a significant advantage for companies grappling with the high costs of R&D. The government's supportive regulations and the availability of skilled medical professionals further contribute to India's attractiveness as a preferred destination for clinical trials.

This favourable ecosystem fosters collaboration between pharmaceutical companies, research institutions, and healthcare providers, reinforcing India's position as a prominent player in the global pharmaceutical landscape. The major players are IQVIA RDS (India), PAREXEL International (India), Icon Clinical Research India, Veeda Clinical Research, Aragen Life Sciences, Abiogenesis Clinpharm and Cliantha Research to name a few.

By investing in advanced research and development, the pharmaceutical industry not only drives innovation but also fuels the growth of clinical trials in India. This symbiotic relationship strengthens India's contribution to the global healthcare ecosystem, ultimately benefiting patients worldwide. it signifies a paradigm shift that is paving the way for more agile, precise, and patient-centric clinical trials in India.

This transformative shift holds immense potential for advancing medical knowledge, improving patient outcomes, and ultimately shaping the future of healthcare in the country. Digital revolution has revolutionized the way clinical trials are conducted, allowing for real-time data acquisition related to safety and toxicity. The ability to rectify any issues promptly in trial design has further facilitated market growth.

Global pharma eyes India for human studies because of the adherence to stringent regulations for patient enrolment pose significant challenges in conducting clinical trials in India, leading to a decrease in demand. The regulatory framework, designed to protect the rights, safety, and wellbeing of trial participants, often results in a long, complex, and resource-intensive patient enrolment process.

Potential participants must meet specific, strict eligibility criteria concerning their health status, age, and medical history. This ensures that only suitable candidates are included in the trials, enhancing the accuracy and reliability of the findings. They must provide informed consent after receiving detailed information about the trial, including potential risks and benefits. While this comprehensive approach safeguards the participants' interests, it can deter some individuals from participating due to concerns or apprehensions.

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