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CRO Reforms: Tilting Scale towards Accelerated Growth & Transparency

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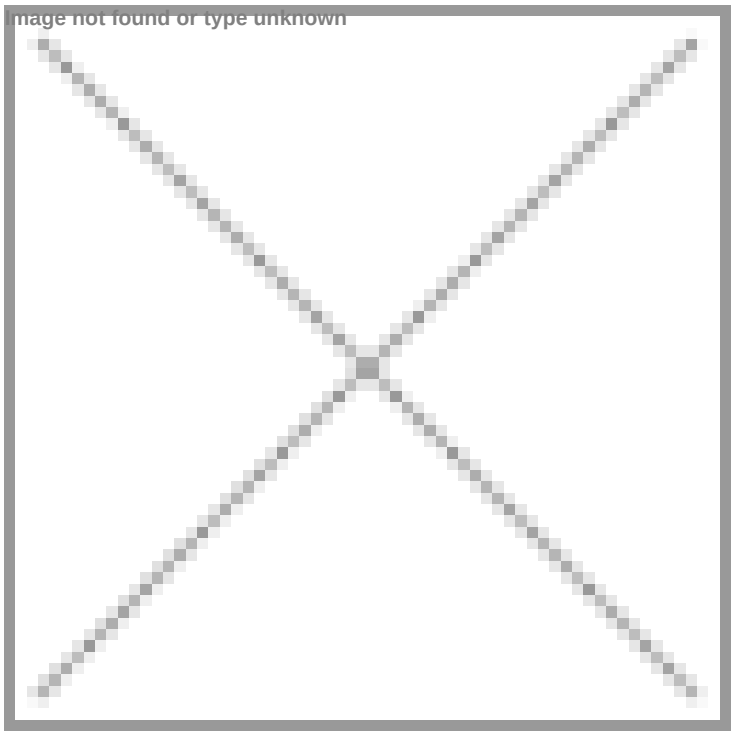
India's clinical research ecosystem is undergoing a major transformation, driven by a wave of regulatory reforms and rapid market expansion. Valued at $2.05 billion in 2024, the country's clinical trials market is projected to grow at a CAGR of 8.64 per cent through 2030. This momentum has made India the third-largest destination for clinical trials globally, with nearly 18,000 new studies registered in 2024, a 50 per cent increase over the year (Invest India).



The 2024 New Drugs & Clinical Trials (Amendment) Rules have received strong support from India's clinical research community, which views them as a pivotal step toward global alignment, efficiency, and greater regulatory clarity.

Sanjay Vyas, President and Managing Director of Parexel India, said, "The 2024 reforms have been a welcome step forward for the sector. Beyond compliance, these reforms create opportunities to explore more complex and adaptive trial designs, to leverage digital and AI-driven solutions for patient engagement, and to build greater capacity across sites and teams. In many ways, they enable us to deepen our role in advancing both India's clinical research capabilities and global drug development efforts."

Over the past five years, Parexel has delivered more than 100 projects in India, supported by a team of over 6,000 professionals. The company's operations span therapeutic areas including oncology, immunology, respiratory and cardiovascular diseases, infectious diseases, and rare disorders. In June 2025, it became one of the first clinical research organisations (CRO) to complete mandatory registration with the CDSCO.

Sharing a similar view, **Rama Kondru, CEO of Veridix,** said, "The 2024 New Drugs & Clinical Trials Amendments are transforming India's CRO landscape, setting higher standards for regulatory clarity, operational excellence, and accountability. While the reforms present short-term challenges, they create significant long-term opportunities for CROs to

lead globally, manage complex trials, and harness technology and innovation to drive a competitive edge. For Emmes, these reforms provide the clarity and stability required to accelerate growth in India, while reaffirming our commitment to patient safety, ethical compliance, and global standards. We view this regulatory evolution as a catalyst for strengthening our leadership in high-quality clinical research. The trial processes will be streamlined with accelerated approval timelines enabling quicker trial starts and reducing time-to-market for sponsors."

Veridix, part of the Emmes Group, plays a key role in India's clinical research ecosystem, supporting Phase I to Phase III and post-market studies across multiple therapeutic areas. Emmes India is a strategic hub for the group's global operations, with expertise in vaccine development and infectious disease research.

Shweta Pradhan, Executive Committee Member of the Indian Society for Clinical Research (ISCR), said "The reforms strengthen trust and accountability across the ecosystem. While we do not conduct clinical research ourselves, we closely collaborate with stakeholders including CROs to improve clinical research capabilities, ensure adherence to regulatory compliance, and ensure participant safety. The 2024 NDCT (Amendment) Rules is a progressive step towards regulatory clarity, predictability and efficiency. With respect to CROs, these reforms enable a more streamlined approval process, cut down the time taken for trials to be initiated in the country, also focus on building trust through focus on patient safety and ensure compliance with global standards. This creates a more conducive environment for both global and local sponsors alongside the important stakeholder—the participants of clinical trials in the country."

ISCR represents clinical research professionals from academia, industry, hospitals, and CROs, advocating for ethical, high-quality research that benefits both science and patients.

Nagalakshmi Shetty, Vice President, Biometrics and India Country Head at ICON plc, added, "The country's regulatory landscape is also evolving rapidly. The health authority is taking deliberate steps to streamline and accelerate the approval process for new drugs and clinical trials, improve patient safety protocols, and ensure compliance with global standards. The NDCT Rules, 2024, aim to enhance the clinical trials landscape in India by providing a structured framework for operation of CROs. By aligning more closely with international standards and addressing critical concerns around patient safety and regulatory efficiency, these amendments enhance India's position as a leading global hub for clinical trials and foster a more transparent, ethical, and credible environment for clinical trials in India."

ICON employs over 4,500 professionals across Chennai, Bengaluru, and Thiruvananthapuram, with remote operations in 18 states. India hosts a major share of ICON's global workforce, which delivers more than 100 specialised services across clinical trial management and drug development. In the past five years, ICON has conducted trials in 14 therapeutic areas, including oncology, infectious diseases, vaccines, and cardio-metabolic disorders.

Dr T Pavan Pradeep, CEO of Actimus Biosciences, highlighted how the reforms improve sponsor confidence and global competitiveness. "The 2024 NDCT (Amendment) Rules represent a significant step forward in aligning India's clinical research regulations with global best practices. Enhanced clarity on timelines, regulatory pathways for orphan drugs, and provisions for accelerated approvals are likely to benefit the ecosystem by reducing bottlenecks and enabling more efficient trial execution. For CROs like Actimus Bio, these reforms may help streamline approvals, improve sponsor confidence, and expand opportunities in specialised research areas."

Actimus Bio is a full-service, regulatory-compliant CRO based in India that specialises in the design, conduct, and management of clinical trials across multiple therapeutic areas. The company focuses on bioavailability and bioequivalence studies, Phase I to Phase IV trials, and post-marketing surveillance.

Market Impact

The CROs agree that the New Drugs & Clinical Trials (Amendment) Rules, 2024 came at a pivotal moment for India's clinical research industry. As the country strengthens its position in global drug development, the updated framework is expected to reshape the size, structure, and sophistication of clinical research being conducted.

Sharing more details Shweta explained, "We see potential for expansion in more innovative spaces such as rare diseases, oncology, vaccine development, and advanced modalities like cell and gene therapy. The revised framework allows for parallel or accelerated approvals of new drugs, eliminating redundant studies and reducing time and cost inefficiencies. This directly benefits patients by bringing innovative medicines, including those targeting rare diseases, oncology, and emerging therapeutic areas such as cell and gene therapy, to market faster."

India's clinical research ecosystem is seeing rapid growth in innovative areas such as cell and gene therapies, tri-specific antibodies, etc. While these areas require specialised infrastructure and trained talent, they represent significant new

opportunities for CROs.

Early-phase research is emerging as a major area of growth under the new regulatory framework. Dr Pradeep Kumar noted, “We anticipate a surge in early-phase trials and greater interest in India as a preferred destination for multi-regional clinical trials (MRCTs). This creates new opportunities for CROs to offer specialised services and partner in complex study designs.”

The reforms are also seen as instrumental in diversifying trial formats. Vyas added, “Early-phase trials, including Phase I studies, may expand, while decentralised and technology-driven trials may become more prevalent, supporting improved patient access and data quality. The rules also require CROs to maintain trial records for at least five years, ensuring long-term accountability and integrity of data.”

Perhaps the most significant structural change is the mandatory registration of CROs. Shweta highlighted, “The significant update in 2024 was the mandatory registration of all Contract Research Organisations operating in India. This registration aligns with the Indian government’s initiative to bring greater transparency and accountability to the Contract Research Organisations sector. By mandating registration with the CDSCO, the government aims to ensure high-quality, ethically conducted clinical trials that generate reliable data and foster global confidence in India’s research ecosystem.”

The reform is expected to create a competitive advantage for compliant players. “Registered CROs will now have a competitive advantage. With compliance, quality standards, and formal registration, CROs can attract global sponsors, expand their service offerings, and participate in more complex, global trials. By formalising CRO oversight and aligning with international Good Clinical Practice (GCP) standards, the rules position India’s credibility as a prime destination for global clinical research,” said Vyas.

Key Challenges and Opportunities for CROs

Moving forward, India’s clinical research sector is expected to experience rapid growth but also profound transformation. The new amendments have ushered in a new era of regulatory rigour, formalising the operations of CROs and establishing higher standards of compliance and data integrity. While these changes have opened fresh opportunities, they also present a set of formidable challenges for the industry.

“In the next 3–5 years, key challenges for Indian CROs will include navigating increasing complexity in trial protocols, ensuring data integrity and compliance amid rising scrutiny from both domestic and international regulators, and talent acquisition and retention in niche scientific and regulatory roles,” said Dr Pradeep.

As trial designs become more complex and patient-centric, CROs are grappling with operational demands that extend far beyond traditional trial management. “On the other hand, CROs will also face challenges, including maintaining regulatory compliance, ensuring high-quality data, and managing increasingly complex multi-site trials. Operational efficiency and skilled workforce readiness will remain the biggest challenge as trial designs evolve and patient expectations increase. Emerging technology, particularly AI and ML, will fill in the gaps and present adaptable solutions to many of these challenges,” said Vyas.

Building a future-ready workforce has become one of the industry’s top priorities. Investment in workforce upskilling is essential. According to Parexel’s recent survey studying the trends impacting the clinical research labor force, one in five biopharmaceutical believe the drug development workforce is well prepared to use AI. Upskilling programmes that focus on critical evaluation, understanding AI limitations, and integrating outputs into decision-making will be key.

Workforce development is only one part of a broader structural shift. “Over the next few years, CROs in India will navigate both rapid growth and structural transformation. Key challenges include upskilling employees and investigators, strengthening data quality and completeness, and enhancing digital infrastructure at hospitals to enable seamless adoption of electronic medical records and automated data capture systems. These steps are essential to align with international standards and ensure reliable, globally acceptable research outcomes,” said Shweta.

As the country moves toward becoming a hub for large-scale trial execution, the industry faces greater scrutiny and responsibility. “Over the next three to five years, India’s CRO sector will grow rapidly — but with far greater regulatory discipline. Stronger oversight, higher sponsor expectations, and India’s position as a hub for large-scale trial execution will drive more complex studies into the country. At the same time, CROs will face increased pressure to meet stricter standards for compliance, data integrity, and operational readiness,” said Kondru.

The new rules make formal registration and audit readiness mandatory, placing a greater burden on smaller players and likely accelerating industry consolidation.

Despite these challenges, industry leaders agree that the opportunities ahead are immense. “The sector is also ripe with opportunities: growing demand for decentralised and hybrid trials, increasing biopharma interest in India for cost-effective, high-quality research, and strategic partnerships with global sponsors looking for regional CRO capabilities. Clearer CRO registration and defined responsibilities provide faster trial initiation, and the ability to expand early-phase, decentralized, and complex trials,” said Dr Pradeep.

The overall outlook remains positive, particularly for organisations with strong scientific and operational capabilities.

Technology & Innovation in Clinical Research

Technology has become a defining force in reshaping global clinical research, and India is no exception. One of the key features of the New Drugs & Clinical Trials (Amendment) Rules, 2024 is the focus on digital transformation and the integration of advanced technologies across the clinical trial lifecycle. All CROs agree that the adoption of e-clinical platforms, digital recordkeeping, and AI-driven analytics is no longer optional; it has become fundamental to how modern trials are designed, monitored, and executed.

“In this new environment, CROs that offer validated e-clinical platforms, centralised monitoring, and AI-driven analytics—from site risk scoring to automated data cleaning—will be positioned to secure premium partnerships. We are uniquely prepared for this shift,” said Kondru.

Technology particularly artificial intelligence (AI) and machine learning (ML) is set to play a transformative role by optimising patient recruitment and site selection using real-world data, enhancing safety signal detection and pharmacovigilance, and enabling predictive analytics for trial design and operational efficiency.

“AI and ML allow CROs to process and interpret vast datasets in real time, make faster and more informed decisions as trials progress, and ultimately improve operational efficiency. However, organisations are encouraged to adopt human-in-the-lead AI frameworks, where human oversight guides and critically assesses AI outputs rather than replacing them,” said Vyas.

Nagalakshmi emphasises the transformative impact of AI and machine learning on clinical research operations. “AI-driven protocol optimisation uses historical data to create more efficient study designs, while advanced data ingestion frameworks integrate diverse datasets for real-time insights and seamless trial execution. Predictive analytics improve trial planning by forecasting patient recruitment, dropout risks, and outcomes. Automated data capture enhances data integrity by minimising manual errors”, says Nagalakshmi.

She adds, “Risk-Based Quality Management (RBQM) powered by AI proactively identifies and mitigates risks, streamlining compliance and reducing operational burdens. Similarly, Risk-Based Monitoring (RBM) optimises resource allocation by pinpointing high-risk sites. Additionally, AI-driven imaging and diagnostics provide faster, more precise assessments in complex fields like oncology and radiology, redefining the efficiency and accuracy of clinical trials”.

Kondru summed up, “Technology will be the key differentiator. AI and machine learning are reshaping trial execution by enabling real-time risk detection, anomaly tracking, and predictive decision-making. At Emmes, we are already integrating Veridix’s AI-based platforms into our operations, delivering higher data accuracy, proactive monitoring, faster study execution, and automating regulatory compliance. By pairing innovation with compliance excellence, we are setting a new benchmark for how clinical research should be run—efficient, reliable, and impactful.”

The New Drugs and Clinical Trials (Amendment) Rules, 2024 represents a pivotal moment in India’s journey toward becoming a global leader in clinical research. Beyond the procedural efficiencies and ethical safeguards, the amendments open the door to transformative business opportunities. By fostering transparency, accountability, and global alignment, the revised rules strengthen India’s appeal as a destination for clinical trials and drug development. The next three to five years will be pivotal as technology and policy converge to redefine the future of clinical development in India.

Ethical concerns

In October 2025, two leading contract research organisations (CROs) based in Ahmedabad came under investigation after reports of irregularities in ongoing drug trials. Preliminary findings point to multiple ethical lapses — including recruitment of

volunteers through informal agents offering cash incentives, incomplete informed consent procedures, inadequate post-trial follow-up, and data management using non-licensed software. Allegations also mention excessive blood draws and recruitment practices extending across districts.

The Ahmedabad Municipal Corporation (AMC) and the Gujarat Food and Drug Control Administration (FDCA) have initiated formal reviews, while the Central Drugs Standard Control Organisation (CDSCO) has been notified.

A similar case surfaced earlier in July 2025, when the Karnataka government requested a CDSCO probe into alleged trial violations at a Bengaluru-based hospital group. The complaint was originally raised by the former head of its ethics committee. These incidents have renewed attention on the need for stronger oversight and ethics governance in India’s clinical research sector.

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