BioSpectrum the business of Bio & Health Sciences

AI accelerating clinical trials in India

13 August 2025 | Views | By Chandra Ambadipudi, Co-founder and CEO, ClairLabs

India stands ready to redefine global clinical innovation

For decades, the progress of clinical trials worldwide has been hindered by prolonged timelines and excessive cost overruns that persist. From clinical researchers to biopharmaceutical manufacturers and genomics-led organiaations, the priorities are clear: accelerating drug development, improving patient outcomes, and optimising resource allocation.

As health and life science companies in India enter the next phase of the Artificial Intelligence (AI) and Data revolution, it is no longer about how clinical trials are designed, conducted, or analysed; it is about doing all of it with enhanced precision and efficiency. With a burgeoning market rate of 8% from 2025 to 2030, India is poised to become a key R&D hub. But with every opportunity comes a considerable number of roadblocks.

What's hindering India's evolution into a global Clinical trial hub?

The rich cultural and genealogical diversity of India is a favorable factor for most researchers, but it can also be daunting to handle datasets stemming from such a massive population. Besides posing logistical challenges, profiling, recruiting, and retaining participants with varying socio-economic backgrounds and health literacy levels is also a Herculean task! Other challenges include:

Low Participation vs. High Disease Burden

While India accounts for ~20?% of the global respiratory infection burden, only 3?% related trials are held; similar gaps exist in cardiovascular (14?% vs. 4?%) and diabetes (19?% vs. 8?%) studies.

Data silos and inaccuracy

Fragmented, siloed, and low-quality data can significantly impact insight extraction in AI/ML-based clinical trial management systems, leading to flawed trial outcomes, compromised patient safety, and substantial penalties.

AI bias

AI models with biased data and algorithms can favor certain demographics, or hallucinations can further produce inaccurate predictions, which can negatively impact the reliability and generalisability of AI-driven clinical trial processes, leading to inequitable outcomes.

Workforce shortage and digital divide

Currently, there's an acute shortage of skilled professionals who are adept at digital technologies and modern research methodologies. With the increasing reliance on digital technologies, a limited percentage of employees who can navigate digital-centric, data-led decentralized trials can have an adverse impact on the quality of trials and data management.

Regulatory hurdles

Frequently evolving regulatory guidelines and updates to global clinical trial policies pose a huge challenge as organizations scramble to keep pace with them. Apart from uncertainty, delays, and inequitable outcomes, institutions must also encounter heavy legal and financial repercussions.

Uncovering opportunities for better global health

Accelerating patient recruitment, optimising trial design, and enhancing data analysis – these are the key objectives that today's health and life science research leaders are seeking out. Moreover, upscaled regulatory reforms, including the New Drugs and Clinical Trial Rules (NDCT) 2019, have reduced approval timelines by 30–40%, increased Phase IV study growth by 4% annually, and expanded site counts by 40%, thereby reigniting global sponsor interest.

AI-Powered Clinical Trial Acceleration: AI-driven recruitment slashes screening time, predictive modeling refines protocols for higher success rates, continuous safety monitoring safeguards participants, and automated data analytics uncovers actionable insights. Thus, sponsors and research teams in India can conduct faster, more cost-efficient, and patient-focused trials. For instance, Novo Nordisk shifted 33?% of its global diabetes R&D to India, driving a 60?% increase in local trial activity from 2014 to 2020 through partnerships with academic and hospital networks.

Focus on Decentralised Trials: With wearables and mobile apps gaining popularity, embedding AI advancements in them can enable personnel to run continuous remote monitoring and dynamic protocol adjustments. This, in turn, enables institutions to make trials accessible and convenient, especially for underserved populations. Eli Lilly's Sintilimab study added Indian Phase III cohorts to diversify the population data for its PD-1 inhibitor, following FDA guidance on China-only trials.

Personalised Medicine: health histories, genomic profiles, and biomarker data – AI can help researchers identify optimal treatment modalities for each patient. Besides enhancing therapeutic efficacy, firms can minimise adverse effects and drive measurable improvements in both clinical outcomes and R&D productivity.

Generative AI Advancements: World Economic Forum reports that Gen AI is poised to transform trial design and operations—drafting optimised protocols, forecasting recruitment potential, and synthesising complex operational datasets. These capabilities accelerate decision?making and resource allocation, making trials more adaptive and aligned with

strategic goals.

Ethical AI Development: As AI's role in clinical trials deepens, establishing ethical frameworks ensures transparency, fairness, and accountability. Collaborative efforts among regulators, sponsors, and CROs are essential to define governance standards that protect patient data, uphold consent, and maintain public trust.

Reimagining care from the ground up

Recent studies cite that AI integration can reduce trial timelines by up to 30% and data processing by 70% . Targeted upskilling, adaptive regulations, and governance can help research firms unlock opportunities in decentralized trials and precision medicine. With surging investments in cloud infrastructure and AI services, magnates such as Pfizer, Sun Pharma, Roche, and Novartis are eager to fast-track and streamline clinical trials in India. Sponsors and CROs can leverage AI and analytics-powered NGS Diagnostics platforms to conduct cost-effective, patient-centric studies. Another promising milestone is the IndiaAI mission, launched on March 7, 2024, which establishes new AI-for-healthcare centres at AIIMS and IITs to bolster the country's AI ecosystem. Poised at the AI–life sciences nexus, India stands ready to redefine global clinical innovation—a momentum that can accelerate patient access to breakthrough therapies.

Chandra Ambadipudi, Co-founder and CEO, ClairLabs