

## Research Brief

# Decentralised clinical trials in India: Stakeholders' perspectives

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**Background and objectives:** Decentralised clinical trials leverage digital technologies to enhance trial accessibility, patient engagement, and improve operational efficiency in clinical research. This study assesses the adoption of these trials among 47 Indian clinical research site professionals from a global survey (n=288).

**Methods:** A sub-analysis of a global cross-sectional survey conducted between August–September 2024 assessed respondents' roles, experience, trial types, therapeutic areas, perceived benefits, challenges, patient satisfaction, and expectations from the Indian researchers involved in decentralised clinical trials. Data were analysed using descriptive statistics, weighted averages (scale: 1=significant challenge to 5=significant benefit), and mean rank analysis.

**Results:** Hybrid trials (n=33;71%) were more prevalent than full trials (n=14;29%). Frequently adopted components included home health visits and remote monitoring (n=10;16% each), particularly in oncology (n=8;17%) and cardiovascular trials (n=7;15%). Key perceived benefits included improved patient convenience (mean score: 3.8) and enhanced participant diversity (3.5). The most significant challenges were limited digital literacy (2.3) and regulatory uncertainty (mean rank 6.1). Patient satisfaction averaged 4.0, with 83% of respondents anticipating continued growth in adoption of hybrid trials.

**Interpretation and conclusions:** Hybrid decentralised clinical trials offer promising avenues to enhance inclusivity and efficiency in India's clinical research landscape, especially for non-communicable diseases. Gaps in digital literacy and regulatory uncertainties hinder their scale-up. Strategic investments in workforce training, digital infrastructure, and regulatory clarity are critical to unlocking the full potential of decentralised trials.

**Keywords** Decentralised clinical trials; Digital health; India; Patient-centric research; Regulatory compliance; Telemedicine

Clinical trials are vital for advancing medical science, but traditional site-based models often require extensive travel and incur high costs, which can exclude many patients - particularly those in rural or underserved areas. For instance, over 60% of rural patients are excluded due to travel distances averaging 100 km to trial sites. Decentralised clinical trials aim to overcome these barriers by employing digital tools, such as telemedicine, wearable devices, and remote data collection, to enable trial participation from patients' homes. This approach enhances both accessibility and inclusivity.<sup>1</sup>

Decentralised clinical trials are implemented in two formats: full decentralised clinical trials, conducted entirely remotely with varieties of decentralised

elements like telemedicine, mobile technologies to record data, shipping of medicine home *etc.* and hybrid decentralised clinical trials, which integrate both site-based and decentralised elements. By minimising or eliminating the need for in-person site visits, these models reduce logistical burdens on participants and increase engagement.<sup>2</sup>

India's clinical trials market is expected to expand from USD 2.05 billion in 2024 to USD 3.37 billion by 2030, growing at a CAGR of 8.6%.<sup>3</sup> Regulatory reforms led by the Central Drugs Standard Control Organization (CDSCO), particularly the 2019 New Drugs and Clinical Trials Rules, have strengthened India's position by streamlining trial approvals and reducing timelines to 30 days for domestic and 90 days for global clinical

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trials, making the country an increasingly attractive destination for global clinical studies.<sup>4</sup> This study examines implementation of decentralised clinical trials in India from the perspectives of clinical research site professionals. It explores adoption patterns, perceived benefits, challenges, patient feedback, and future directions. These insights aim to inform strategies for strengthening India's clinical research ecosystem and positioning it as a global leader in patient-centric research.

### Methods

This study was undertaken by the department of Clinical Research, Texila American University, Guyana, South America. This sub-analysis was conducted under ethical approval granted by the ACE Independent Ethics Committee, Bengaluru, India.

*Study design:* This study presents a sub-analysis of responses from Indian clinical research site professionals (n=47) extracted from a broader global survey (total respondents n=288) on decentralised clinical trials conducted between August and September 2024. The analysis focused on responses from principal investigators, sub-investigators and study coordinators actively engaged in clinical trials.

*Survey instrument:* The survey evaluated various aspects of decentralised clinical trials, including respondent characteristics (role, experiences), implementation models (type and elements used), therapeutic areas and trial phases, perceived benefits and challenges, patient satisfaction, and future expectations. The questionnaire was developed based on a review of published literature and input from clinical research experts experienced in decentralised clinical trials, pilot-tested among nine respondents from Denmark and India, and refined based on their feedback to ensure clarity and feasibility.

*Data collection:* Data were collected via Survey Monkey during the global survey period (August 6 to September 9, 2024). The survey employed convenience and snowball sampling techniques, disseminated through professional networks, email, WhatsApp, and social media platforms such as LinkedIn and Facebook. Participation was voluntary, and all responses were anonymised.

*Statistical analysis:* Quantitative data were analysed using descriptive statistics. This included frequencies and proportions for categorical variables (e.g., respondent roles, DCT types, therapeutic areas), weighted means for Likert-scale items (1=significant challenge to 5=significant benefit) to assess perceived

benefits, challenges, and satisfaction levels, and mean rank analysis to prioritise perceived barriers and strategic needs.

### Results

*Respondent characteristics:* Principal investigators comprised the largest group (n=24; 51%), followed by study coordinators (n=15; 32%), and sub-investigators (n=8; 17%).

*Adoption and implementation:* Hybrid decentralised clinical trials, combining remote and in-person trial components emerged as the most adopted model, reported by ~33 (71%) respondents. Full trials were adopted by 14 (29%).

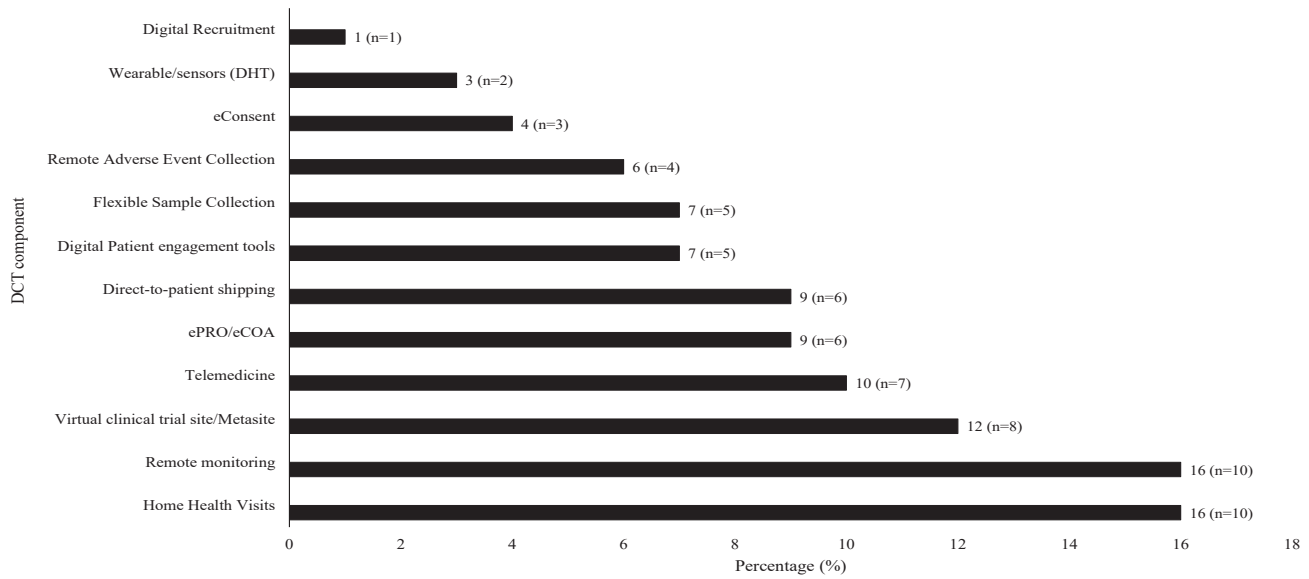
The utilisation of specific elements of decentralization varied, as illustrated in the **Figure**. Home health visits and remote monitoring were the most frequently used components, each cited by 10 respondents (16% of total responses). Other commonly adopted elements included virtual sites, electronic patient-reported outcomes (ePRO) and telemedicine, reflecting the growing integration of digital tools in trial workflows.

*Therapeutic areas, trial phases and duration:* Implementation of decentralised clinical trials in India showed a distinct concentration within specific therapeutic areas and trial phases. Oncology trials accounted for the highest proportion (17%), followed by cardiovascular diseases (15%) and metabolic disorders (15%), respiratory diseases (13%), immunology/infectious diseases (10%), neurology (10%), dermatology (8%), rare diseases (6%), rheumatology (4%) and optometry (2%).

Phase 3 trials accounted for the largest share (n=12; 40%), followed by Phase 4 (n=9; 30%), Phase 2 (n=8; 27%), and only a small proportion in Phase 1 (n=1; 3%).

*Perceived benefits and challenges:* Patient-centric advantages emerged as the most significant perceived benefit of DCTs. Overall costs were rated as the top benefit (mean score of 3.9 out of 5), followed by patient convenience/satisfaction (3.8) and technology integration (3.7). Other notable benefits included real-time data collection (3.6), improved patient retention (3.6) and patient diversity (3.5). Aspects such as data quality (3.1), regulatory compliance (3.2), and site workload (3.2) were perceived neutrally.

Limited patient digital literacy emerged as the most significant challenge, receiving a weighted score of 2.3



**Figure.** Utilisation of components of decentralised clinical trials in India. Here, n=67 responses from 46 respondents. Multiple selections allowed.

**Table. Key barriers to adoption of decentralised clinical trials in India**

Barrier	Weighted mean rank
Inability to measure ROI	6.54
Regulatory uncertainty	6.13
Resistance to change	6.12
Patient preference for traditional trials	5.92
High implementation costs	5.91
Site adoption	5.74
Data quality/privacy concerns	5.35
Technology limitations	4.75
Operational and logistical challenges	4.54
Lack of standardisation	3.96

out of 5. Other notable challenges included maintaining protocol adherence data privacy concerns (2.9) and site staff adaptation (3.0). Key barriers to adoption of decentralised clinical trials are shown in the **Table**.

*Patient satisfaction and future outlook:* Despite challenges, patient satisfaction with these trials was high, with an average score of 4.0 out of 5. Among the 15 respondents providing feedback, 11 indicated patients as satisfied, 2 as very satisfied, and 2 neutral.

Twelve (67%) respondents believed that the hybrid decentralised clinical trials are the most effective approach. Approximately 20 (83%) of respondents anticipated growth in hybrid decentralised clinical

trials. While 13 (57%) respondents anticipate growth in full trials.

Investment in digital infrastructure emerged as the top priority (mean importance rating of 4.3 out of 5), followed by regulatory clarity and enhanced staff training, both scoring 4.2.

### Discussion

This study underscores the transformative potential of decentralised clinical trials in India, revealing a growing preference for hybrid models that improve access to clinical research while navigating persistent digital and regulatory challenges. Three interrelated themes emerged - accessibility and equity, technological and regulatory evolution, and workforce and community readiness - each critical to advancing adoption of decentralised clinical trials in India. However, digital literacy emerged as a significant barrier. Concerns about the authenticity of patient-reported data and limited technological awareness among participants in low-resource settings were frequently cited.<sup>5</sup> Initiatives such as the National Digital Health Mission (NDHM) offer a foundation for expanding digital access. Deliberate efforts are required to ensure equitable reach - particularly through mobile platforms in regional languages, improved rural connectivity, and community-based education programmes.<sup>6</sup>

Establishing a national DCT framework inspired by the US FDA's 2024 guidance could standardise

practices, promote patient safety, and encourage broader adoption.<sup>7</sup> CDSCO's proposed updates to India's Good Clinical Practice (GCP) guidelines, emphasising technology integration and e-consent provisions, indicate regulatory recognition of the need for decentralised clinical trial frameworks.<sup>8</sup> Such a framework should integrate digital tools, data protection protocols under India's Digital Personal Data Protection Act (2023), and provisions for hybrid models. By doing so, India can position itself as a leader in tech-enabled, inclusive research while also fostering economic growth through jobs in telemedicine and app development.<sup>9</sup> Collaboration between CDSCO and the NDHM is essential to align regulatory policies with technological advancements.

Community engagement is equally vital. Several respondents highlighted that in-person visits still offer greater opportunities for detailed patient communication and adverse event reporting, especially in rural settings where remote interactions may be met with scepticism. The value of hybrid models is that they retain human interaction while leveraging digital tools. This preference can significantly impact the accuracy and completeness of adverse event reporting, highlighting the need for hybrid approaches in decentralised clinical trials.<sup>10</sup>

Expanding the roles of community health workers, already trusted intermediaries in rural areas, could enhance trial participation, literacy, and data quality. These workers are uniquely positioned to explain the trial procedures, monitor adherence, and facilitate informed consent in local languages, thereby bridging communication gaps. Patient safety was also highlighted as a potential major challenge, indicating the need for robust safety monitoring protocols in DCT designs. Strategic investments in staff training, community outreach, and patient-centric technologies are essential. Collaborations between sponsors, research institutions, technology providers, and regulatory bodies can enable tailored curricula covering eClinical tools, data privacy, wearable integration, and patient safety. Regional workshops, multilingual apps, and culturally appropriate engagement strategies can foster trust and digital literacy across diverse populations.<sup>11,12</sup>

The findings of this study align with the Indian Society for Clinical Research (ISCR)'s 2023 position paper, which identifies hybrid DCTs as a scalable and patient-centric model suited for India.<sup>13</sup> While enthusiasm for DCTs is growing, systematic

interventions are necessary to address barriers and harness their full potential. A coordinated national strategy that integrates regulatory reform, digital infrastructure, workforce training, and community engagement will be key to sustainable DCT expansion.

While this study provides valuable insights into DCT adoption in India, several limitations warrant acknowledgment. The sample size may not adequately represent the diverse perspectives of the entire Indian clinical research community, which could limit the generalisability of the results. Furthermore, while the study addresses key challenges like digital literacy and regulatory uncertainties, it does not thoroughly explore region-specific barriers or the differing capacities of various institutions, which could offer a more nuanced understanding of DCT implementation across India's diverse landscape.

Despite these limitations, this study demonstrates that DCTs offer a transformative opportunity to enhance patient-centricity, efficiency, and inclusiveness in India's clinical research landscape. However, challenges such as regulatory uncertainties, technological gaps, and socio-cultural barriers remain.

To unlock DCTs' full potential, India must modernise regulations, invest in digital infrastructure, build workforce capacity, and develop inclusive technologies for diverse populations, especially in rural areas. Addressing these challenges strategically will enable India to emerge as a global leader in innovative clinical research. For chronic disease patients in rural India, hybrid DCTs enable trial participation by combining essential in-person clinic visits with remote monitoring. This directly improves accessibility while maintaining clinical rigor. Future studies should validate implementation outcomes and guide policy.

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### शोध-संदेश

विकेंद्रीकृत क्लिनिकल ट्रायल (Clinical Trial), परीक्षणों की सुलभता बढ़ाने, रोगियों की सहभागिता बढ़ाने और क्लिनिकल अनुसंधान में परिचालन दक्षता में सुधार लाने के लिए डिजिटल प्रौद्योगिकियों का लाभ उठाते हैं। हाइब्रिड विकेंद्रीकृत क्लिनिकल ट्रायल, भारत के अनुसंधान परिदृश्य में समावेशिता और दक्षता बढ़ाने के लिए आशाजनक अवसर प्रदान करते हैं, विशेष रूप से गैर संक्रामक रोगों के लिए। डिजिटल साक्षरता की कमी और नियामक अनिश्चितताएं इनके विस्तार में बाधा डालती हैं। कार्यबल प्रशिक्षण, डिजिटल अवसंरचना और नियामक स्पष्टता में रणनीतिक निवेश, विकेंद्रीकृत परीक्षणों की पूर्ण क्षमता को उजागर करने के लिए महत्वपूर्ण हैं।

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