International Journal of Clinical Trials
Tambe AR. Int J Clin Trials. 2025 Aug;12(3):262-269
http://www.ijclinicaltrials.com
pISSN 2349-3240 | eISSN 2349-3259
DOI: https://dx.doi.org/10.18203/2349-3259.ijct20252205

Review Article

Digital transformation of clinical research: facilitating decentralized clinical trials in India

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Received: 10 May 2025
Revised: 11 June 2025
Accepted: 10 July 2025

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ABSTRACT

The decentralized clinical trials make clinical research accessible by using digital tools such as e-consent, telehealth, and remote monitoring. Decentralized clinical trials in India have the potential to reduce participant burden and increase trial participation. However, the nation's disparate healthcare system, digital divide, and changing regulatory environment make broad adoption difficult. The current status of decentralized clinical trials in India is examined in this review, including significant operational, regulatory gaps, and potential implementation strategies. The aim is to offer information which will help in scaling decentralized clinical trials in India. This review compiles findings from journals, regulatory guidelines, white papers, blogs and case studies from Indian decentralized clinical trial platforms. It focuses on trends, logistical challenges, regulatory readiness in decentralized clinical trials implementation in the Indian context. To support key details tables and figures are used. India's pilot decentralized clinical trials demonstrate increased cost-effectiveness and reach, particularly when it comes to extending access outside of cities. However, region-specific infrastructure deficiencies, untrained staff for decentralization operations, and absence of e-consent provisions in New Drugs and Clinical Trial Rules 2019, restricts scalability. The 2024 draft guidance of United States's Food and Drug Administration provides framework for decentralized clinical trials which can be implemented in India. In order to ensure ethical, and successful implementation of decentralized clinical trials for India's diverse healthcare system investment in digital health infrastructure, regulatory revisions, and site personnel training for decentralized clinical trial operations is necessary.

Keywords: Decentralized clinical trials, India, e-consent, Telehealth, Clinical research

INTRODUCTION

Decentralized clinical trials signify a considerable change from more site-centric, traditional clinical research practices to ones that are more adaptive to patient's comfort with the assistance of technology. Around the world, the adoption of decentralized clinical trials has been on the rise, especially post the COVID-19 pandemic, which highlighted the inefficiencies of traditional trial models in accessing and accommodating a large number of population safely and efficiently. By using modern digital technology, such as e-consent, telemedicine, wearable sensors, and remote patient monitoring (RPM), patient engagement and flexibility while preserving the compliance and integrity of the trials has increased.[1] Within the Indian system, the DCT methodology appears to be the most promising solution to geographical digital disparity and site-accessibility issues, which pose challenges such as patient recruitment and retention. Research claims that employing digital and analytics tools into decentralized frameworks can greatly enhance trial running efficiency, reduce costs, and increase the standard of clinical data collection of trials conducted in India.[2] However, there are barriers to the adoption of decentralized clinical trials in India. Apart from the standard ethical and operational challenges that come with any new technology adoption within digitization, these issues are also heightened due to the administration in

India. There is much scholarly literature tracing counterarguments pertaining to the privacy of data, remote informed consent, and equitable access as ethical hurdles restraining the advancement of contemporary medicine.[3]

In addition, maintaining the data quality from contamination and reduction of protocol deviations in a remote clinical trial environment requires advanced planning such as using frameworks like the Estimands approach outlined in reference.[4] Also, India's regulatory and infrastructural decentralized clinical trial execution challenges are not like any others.[5] This review emphasizes the need for clear policies and better trial infrastructure by pointing out the ambiguous regulatory pathways and inadequate primary management. It looks at how decentralized clinical trials are doing in India right now, points out any operational or legal shortcomings, and suggests recommendations to make them widely used.

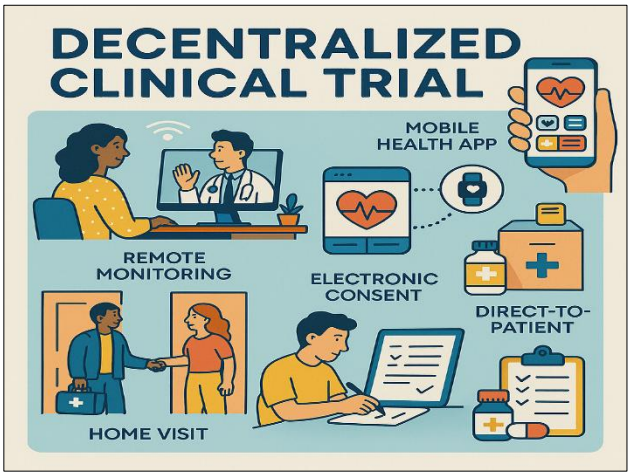

Figure 1: Key components of a decentralized clinical trial.

METHODS

The review was done by employing a literature review approach to search for existing studies, reports, and policy documents on decentralized clinical trials with an emphasis on its application in India. It included the following databases: PubMed, Scopus, Google Scholar, ScienceDirect, and SpringerLink. The keywords and search phrases were: "decentralized clinical trials," "remote clinical trials," "regulatory considerations," "digital health in clinical trials," "operational challenges in decentralized clinical trials." The primary focus of the search was to include only those articles published in English. The functional inclusion criteria consisted of academic articles, regulatory frameworks, case studies, blogs and industry white papers analysing the decentralized clinical trial's implementation, development, regulatory concerns, constraints, or benefits. Exclusion criteria included those articles not discussing human clinical trials, and analysis concentrating solely on traditional site-based studies that do not incorporate or acknowledge decentralization methods. Screening of the articles was done systematically, starting first with the title and abstract followed by the full text. The synthesis of the data was done based on major categories which included but are not limited to: regulatory structure, digital systems, ethics, patient-focused care, as well as operational and other challenges. A total of 29 articles were selected to provide a comprehensive and balanced perspective for this review.

CURRENT TRENDS OF DECENTRALIZED CLINICAL TRIALS IN INDIA

Pharma and contract research organization initiatives

To overcome persistent issues such as patient recruitment, site accessibility, and data collection, pharmaceutical companies and healthcare systems operating in India have started putting decentralized clinical trial models into implementation. These organizations are realizing how technology-driven trial frameworks can increase productivity, reduce trial delays, and improve patient satisfaction in general. An example of this initiative is StriderDCT, a pharmaceutical company that provides a full-featured platform for end-to-end decentralized trial operations. To facilitate real-time data collection, remote patient monitoring, and efficient communication between trial stakeholders and participants, their system incorporates several essential features like electronic source documentation (eSource), electronic informed consent (e-consent), electronic interactive response technology (e-IRT), and telemedicine services.[6]

Additionally, Karkinos Healthcare has become a leader in the use of decentralized clinical trials in oncology trials. Its strategy is based on using decentralized methods to boost the provision of cancer care. This initiative has increased the access to clinical trials and modern treatments, especially for those patients residing in underprivileged or rural areas, thus eliminating the need to relocate or travel long distances. This measure represents a major advancement towards the direction of patient-centred trial design and fair access to state-of-the-art treatments.[7] The Indian pharmaceutical companies and healthcare centres are now highlighting a larger trend of adopting digital innovations for more effective, accessible, and inclusive research. The quality, dependability, and regulatory compliance of the clinical data gathered are greatly enhanced by incorporating technology into clinical trial procedures, which also shortens the trial's overall duration.[8]

Use of telemedicine, e-consent, and home care services

The use of telemedicine, electronic consent (e-consent), and home-based care services have been incorporated into decentralized clinical trial operations in India. The telemedicine facilitates distant consultations, which decreases the need for physical site attendance for patients, e-consent platforms enable the automated process of informed consent which guarantees compliance and

understanding of the subjects of the study, home care services allow clinical procedures to be done in the patient's home, facilitating the participation of patients from various regions for nursing and sample collection.

Incorporating these components enhances the convenience of clinical trials for trial participants in India. This is useful for a large country like India with rural populations and unequal access to the healthcare system. With the wide adoption of these technologies, India can fulfil the requirements of global practices and stand as a competitor in decentralized clinical trials.

Case studies of DCT from Indian institutions

The implementation of decentralized clinical trials in India has been demonstrated by healthcare organizations, which resulted in insightful information about its feasibility and possible impact within the Indian healthcare and research system. An understanding of how decentralized models can be modified to address India's particular geographic and socioeconomic challenges has become easier by these early implementations. For example, the Indian Council of Medical Research (ICMR), one of the nation's leading organizations for biomedical research, has recognized the substantial disparity in digital literacy and proficiency, especially in underprivileged and rural areas, and also how these issues make the successful implementation of decentralized clinical trial approaches difficult. The institution's understanding of the digital divide and its consequences for fair trial access and data quality in decentralized systems is highlighted in this recognition.[9]

Furthermore, the potential of decentralized clinical trials in reducing the long-standing healthcare gaps in rural and underdeveloped regions of the nation has been highlighted by Clival. It emphasized the stark reduction of healthcare services accessibility to these regions and made the case for the value of decentralized clinical trials, as a way to provide timely, reliable healthcare in a virtual manner. The findings of Clival also included success stories of decentralized clinical trial operations that demonstrated how decentralized models have enhanced remote monitoring and facilitated thorough and easily accessible clinical care.[10]

Together, these examples demonstrate the steadily increasing acceptance and implementation of decentralized clinical trials in Indian research institutions, thereby highlighting a rising trend towards clinical research methods that are inclusive, patient-centred as well as technologically sophisticated.

OPERATIONAL GAPS IN DECENTRALIZED CLINICAL TRIALS IN INDIA

Digital divide: rural versus urban disparities

There are significant socioeconomic disparities among India's regions due to country's vast geographic as well as cultural diversity. These issues directly affect the feasibility and efficacy of decentralized clinical trials. Moreover, these disparities have been worsened by a number of geopolitical issues, such as unequal healthcare delivery, regional policy differences, and varying levels of digital initiatives led by the states. One of the biggest challenge is the difference in information and communication technology (ICT) infrastructure between urban and rural areas, which forms the basis of decentralized clinical trial implementation.

According to data from the National Sample Survey Office, only 24% of rural households have internet access, as compared to 66% of urban households (Figure 2). The crucial decentralized clinical trial elements, such as telemedicine consultations, e-consent platforms, and remote patient monitoring tools, rely on dependable internet connectivity and digital literacy.[11]

Also, the lack of infrastructure creates a major obstacle for researchers who are trying to gather real-time data, implement decentralized clinical trial element in the clinical trial operations and maintain regulatory compliance throughout the trial, in addition to restricting patient participation in decentralized trials from rural or underprivileged areas.[12] The restricted access to smart devices and inadequate training of digital tools for site personnel widens the decentralized clinical trial gap between regions.

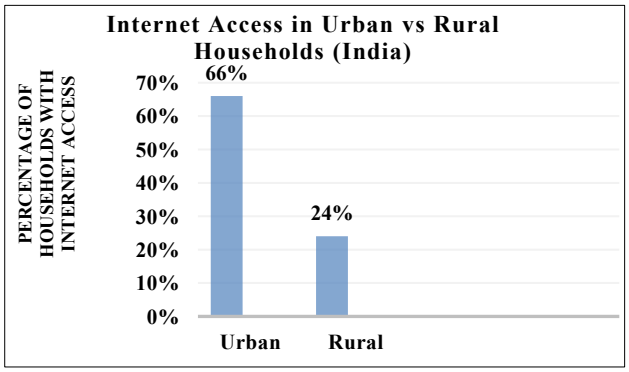

Figure 2: India's urban versus rural household internet access.

Participant onboarding and retention

For the trials to advance successfully, an engagement of participants in clinical trials is crucial. The adoption of decentralized clinical trials facilitates convenience by minimizing the need for travel to participants and offering flexibility, there are challenges regarding the onboarding and retention of participants. These difficulties often arise due to limited digital literacy among certain populations, especially the elderly ones or those from rural or underprivileged regions. Moreover, there is an absence of a personal connection that is typically fostered in traditional site-based trials. The research indicates that the average dropout rate of participants in clinical trials is

approximately 30%, which not only inflates trial costs but also jeopardizes the integrity of the data collected and the overall validity of the study outcomes.[13]

It is essential to counter this challenge for the ethical, effective and successful implementation of decentralized clinical trials in the diverse population of India. Also ensuring the participant's comfort and confidence in using the digital tools provided is crucial to improve their engagement and retention rates in decentralized clinical trials.[14]

Training of investigators and staff

The training of investigators and staff regarding the sustainability of decentralized clinical trials relies on the adoption of technological solutions to streamline tasks that have been traditionally done manually. A PwC report emphasized the need for decentralized clinical trial-focused clinical trials for investigators and staff, suggesting that the development of complete training for decentralized clinical trials is crucial.[15]

Digital patient involvement tools, advanced remote and in-person patient administration and patient interfacing devices are critical components of the modernized training curricula, yet these training methods may not be implemented in the older decentralized frameworks.[16]

Logistics for drug delivery and sample collection

The successful functioning of decentralized clinical trials relies on efficient logistics, with respect to the delivery of investigational products. For example, due to India's diverse geographical regions and infrastructural limitations, the timely and compliant delivery of temperature-sensitive investigational products and biological samples can be challenging. Remote and rural areas may lack proper cold chain systems, increasing the risk of compromised samples or delays. The high pharma logistics costs hinder remote decentralized clinical trial feasibility and raise concerns about scalability and consistency in such settings.[17]

These issues can be mitigated by adopting direct-to-patient (DTP) models, which allow trial materials to be shipped directly to participants, reducing reliance on centralized sites, and by collaborating with specialized logistics companies that understand clinical trial requirements.[18] An example is provided by Dalsey, Hillblom and Lynn (DHL), a multinational logistics brand that places a great focus on patient-focused supply chains to maintain the continuity and prompt delivery of clinical trial materials, while ensuring temperature control, timely handover, and compliance with trial protocols.[19]

Table 1 highlights the challenges that hinder the efficient adoption of decentralized clinical trial in the Indian context.

Table 1: Operational gaps in decentralized clinical trial implementation in India.[11,12,15,19]

Gap	Description	Impact
Digital divide	Low levels of digital literacy and insufficient ICT infrastructure are prevalent in rural areas.	Restricts the participation of rural population in DCT, leading to their underrepresentation in trials.
Training needs	Lack of specialized training in DCT techniques.	Results in protocol violations and ineffective trial conduct.
Logistics challenges	India's total pharmaceutical logistics costs is approximately 7–10%	Impacting DCT feasibility for remote regions.
Participant retention	Low familiarity with digital technologies and a lack of in-person interactions	Increases dropout rates and undermines the accuracy of the data.

Data is derived from the operational gaps in decentralized clinical trials in India, discussed in the article text with cited references

REGULATORY CONSIDERATIONS FOR DECENTRALIZED CLINICAL TRIALS IN INDIA

NDCTR 2019: does it accommodate DCT models?

The Central Drugs Standard Control Organization (CDSCO), India's regulatory authority, introduced the New Drugs and Clinical Trials Rules (NDCTR) 2019, which led to a significant step in the regulation of clinical trials in India. The creation of this regulatory framework was designed to promote transparency, expedite the clinical trial approval process, and align India's clinical research standards with international norms. The primary focus of NDCTR, 2019 is on conventional, site-based trial models, it provides extensive guidelines for the moral and scientific conduct of clinical trials. However, it does not offer specific recommendations tailored to the changing environment of decentralized clinical trials, which include remote and virtual modalities as essential elements.[20] The current version of NDCTR does not address the essential aspects of decentralized clinical trials such as electronic informed consent (e-consent), virtual site visits, telemedicine consultations for patient interaction, remote monitoring by investigators, and the direct-to-patient (DTP) shipment of investigational products. This regulatory gap leads to uncertainty among stakeholders seeking to implement decentralized clinical trial components by adhering to national regulations. In the absence of well-defined protocols or permissions, the integration of digital and decentralized components into

trial designs is challenging for sponsors and investigators, particularly when focusing on patient safety regulations, data integrity, protocols, and ethics approval processes.[21]

Ethics committee guidelines: telemedicine and remote consent

An ethics committee's important aspect of work is the protection of participants' rights and their ethical involvement in clinical trials. The Telemedicine Practice Guidelines issued by the Ministry of Health and Family Welfare in March, 2020 serve as a foundational guide to remote consultations.[22] However, new ethical issues seem to be posed by innovations like telemedicine and remote consent technologies in decentralized clinical trials studies.[23]

The primary focus of these guidelines is on clinical care and does not extend to the specific requirements of decentralized clinical research, such as obtaining informed consent electronically. The absence of explicit guidance on e-consent procedures, data monitoring, and privacy within the context of clinical trials hampers the ability of ethics committee to assess and approve decentralized clinical trial protocols.[24]

To ensure ethical integrity, there is a pressing need for comprehensive guidelines that address these emerging aspects of decentralized clinical trials.

Comparison with US FDA and EMA policies

The international regulatory authorities have taken necessary actions to assist the sponsors in the implementation of decentralized clinical trial operations. For instance, the US Food and Drug Administration (FDA) issued a guidance document in September 2024, relating to detailed recommendations on decentralized components in clinical trials. This guidance aids in the remote collection of clinical trial data and telehealth appointments, as well as electronic informed consent processes, thus offering a clear path for sponsors and investigators with constraints.[25]

Similarly, in the year 2022, the European Medicines Agency (EMA), in collaboration with the European Commission and the Heads of Medicines Agencies as a collective, provided recommended frameworks for the use of decentralized clinical trials in the European Union (EU). These recommendations were focused on participant safety, data integrity, and the overall robustness of trial results and were derived by the incorporation of some decentralized strategies.[26]

Unlike India, which has no defined rules concerning the use of decentralized clinical trials, the wide implementation of its approaches may slow down, therefore impacting India's position in the global clinical research arena.

FUTURE DIRECTIONS AND RECOMMENDATIONS

Need for clear regulatory frameworks

The landscape for clinical trials in India has undergone notable changes due to the execution of New Drugs and Clinical Trials Rules, 2019, which aims to simplify processes and increase transparency in clinical research. However, specific instructions governing some aspects of decentralized clinical trials, for example, remote consent procedures, incorporation of telemedicine, and digital data management are still lacking. Therefore, comprehensive policies specifically designed for decentralized clinical trials are essential for maintaining ethical standards, safeguarding participants, and ensuring the accuracy of the data collected.[27] In the absence of clear regulatory direction, sponsors and investigators face ambiguity in implementing decentralized elements. Thereby, leading to inconsistent practices and potential ethical challenges. For instance, there can be compromise in data integrity and participant safety due to difference in interpretations of electronic consent validity and site responsibilities in virtual environments. Therefore, development of regulatory frameworks that offer clarity on decentralized workflows, acceptable technologies, data privacy protections, and oversight mechanisms is necessary. Also, in order to facilitate multinational trial collaboration and promote best practices within India's evolving clinical research system, harmonization with global regulatory standards, such as those issued by the Food and Drug Administration and European Medicines Agency is crucial. Therefore, structured guidance documents, stakeholder consultations, and periodic regulatory updates will further strengthen the foundation for sustainable and ethical decentralized trials in India.

Importance of public-private partnerships

To speed up the adoption of decentralized clinical trials in India, the public-private partnerships can be fostered by combining resources, knowledge and infrastructure. This collaboration will not only support the development of harmonized standards but also interoperable digital platforms and digital training courses for investigators and site staff. Hence, for addressing clinical research-related problems this collaboration is essential, thereby ensuring consistent implementation of decentralized clinical trial across different healthcare settings in the Indian context. Therefore, by promoting ethical standards, patient-centred behaviour and innovation, these coordinated efforts can ensure the long-term sustainability and scalability of decentralized clinical trials nationwide.[28]

Investment in training and digital infrastructure

For the successful implementation of decentralized clinical trials, building a strong and secure digital infrastructure is essential. Developing digital infrastructure not only

includes cloud-based data repositories, secure platforms for real-time data sharing and remote monitoring, and interoperable electronic medical records (EMRs), but also dependable internet connectivity in all geographic locations, particularly in rural and underprivileged areas is necessary. These technologies guarantee adherence to trial protocols and data privacy laws and also facilitate smooth coordination between sponsors, investigators and participants.

The backbone of decentralized clinical trial operations includes elements such as teleconsultations, e-consent, mobile health app, remote monitoring and direct-to-patient delivery of investigational products. However, these digital technologies are not sufficient alone. The development and rollout of comprehensive training programs for digital technologies for investigators, site staff, and study coordinators is equally crucial. The training modules should incorporate both the operational use of decentralized clinical trial-specific technologies and the ethical and regulatory frameworks associated with remote clinical research.

Hence, this dual emphasis on infrastructure and human resource capacity can ensure that all the stakeholders of clinical research can confidently manage decentralized elements, minimize protocol deviations, and maintain high standards of patient safety and data integrity throughout the study lifecycle. Without such foundational investments, the scalability and sustainability of decentralized clinical trials remain uncertain, especially in a diverse and fragmented healthcare system like India's.[7]

Pilot programs to assess feasibility

The pilot programs must be carried out to assess the viability, acceptability, and efficacy of decentralized clinical trial approaches in the Indian context. These programs can serve as a critical foundation for understanding how decentralized methodologies function within India's diverse healthcare system, by considering regional disparities in infrastructure, patient literacy, and digital readiness. Additionally, these pilot programs may allow real-world testing of digital tools, remote patient monitoring systems, telemedicine protocols, and direct-to-patient logistics in varied socio-economic settings. The insights assessed from such programs can guide the making of necessary modifications in decentralized clinical trial design, implementation strategies, and regulatory compliance mechanisms. Importantly, pilot studies can provide concrete evidence to policymakers and sponsors thereby, validating the scalability of decentralized clinical trial models and helping to build institutional trust in DCT, which is essential for its wider adoption across the country.[29]

Table 2 summarizes key actions to support ethical, scalable, and efficient implementation of decentralized clinical trials across diverse regions of India.

Table 2: Strategic priorities for advancing decentralized clinical trials in India.[7,27-29]

Priority area	Strategic focus
Regulatory adaptation	Add DCT-specific provisions to the existing clinical trial regulations
Collaborative ecosystem	Facilitate collaborative efforts for knowledge sharing, SOP development, and infrastructure
Workforce readiness	Using digital competency programs, upskill trial staff
Feasibility assessment	Start pilot projects to improve procedures and validate implementation models

The strategic priorities summarized in this table are derived from the future directions and recommendations discussed in the article text with cited references

CONCLUSION

By the utilization of digital tools like telemedicine, e-consent, and remote monitoring, decentralized clinical trials are gradually altering the clinical research system in India. This review highlights the potential benefits of early adoption of decentralized clinical trial by pharmaceutical companies and research institutions such as improved patient access, reduced site burden, and enhanced continuity of clinical research during disruptions such as the COVID-19 pandemic. However, there are a number of interrelated barriers which prevent widespread adoption of decentralized clinical trial in the Indian context.

The operational constraints, such as disparate digital infrastructure, particularly in rural and underprivileged areas, lack of digital technology qualified- personnel in scattered locations and insufficient logistical support continue to impede the scalability of decentralized clinical trial. Moreover, regulatory ambiguity, especially the New Drugs and Clinical Trials Rules (NDCTR) 2019, lacks guidance on e-consent and decentralized oversight, which exacerbates stakeholder hesitancy.

Regardless of these drawbacks, it is evident that decentralized clinical trials have the ability to homogenize access to clinical research in India. Therefore, to achieve this potential the country must invest in strengthening its digital health infrastructure, develop pilot programs specific to specific contexts, and boost public-private partnerships. Also, regulatory agency must design thorough India-specific guidance by referring to international frameworks, such as the U.S. Food and Drug Administration's decentralized clinical trial draft 2024, which considers the evolving nature of such trials.

Also, for transition decentralized clinical trials from experimental pilots to a long-term part of India's clinical research system, the creation of standardized protocols, site staff capacity-building programs, and structured operational models will be necessary. Future clinical trials could be greatly impacted by the adoption of decentralized

clinical trials if policymakers collaborate to make commitment to inclusive, cutting-edge solutions.

ACKNOWLEDGEMENTS

Author would like to thank Prof. Renuka Jagtap, Professor of MSc. Clinical Research at Ajeenkya D.Y. Patil University, for her valuable guidance and encouragement throughout the preparation of this review article.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: Not required

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Cite this article as: Tambe AR. Digital transformation of clinical research: facilitating decentralized clinical trials in India. Int J Clin Trials 2025;12(3):262-9.