

## A Cross-Sectional Survey among Clinical Researchers to Assess the Perceived Benefits and Barriers in Adoption and Implementation of Decentralized Clinical Trials in India

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### Abstract

Decentralized clinical trials (DCTs) use technology and knowledge advancements to conduct clinical trials or trials of specific activities when compared to the traditional trial location. During the pandemic and currently, the use of DCTs has been widely implemented globally. Despite the global momentum, their adoption in India remains restricted. The purpose of this study is to evaluate the awareness and understanding of the DCTS and to assess perceived benefits and barriers among clinical research professionals in India with respect to their adoption and implementation. A questionnaire with a cross-sectional approach has been developed using Google forms and was distributed to clinical research professionals across India; 112 clinical researcher's responses were received. We evaluated the responses using descriptive statistics and thematic analysis. The result indicates a high level of awareness (70.5%), while 28.6% are 'somewhat familiar' with DCTs among clinical researchers in India. Most respondents, around 72%, have previously participated in the conduct of DCTs and possess hands-on experience in managing such trials. Hybrid trial design was more prevalent in most therapeutic areas compared to traditional and fully decentralized trials. Most respondents perceived that the key benefits of decentralized clinical trials (DCTs) included improved access to a diverse patient pool and faster data collection and analysis, which were noted by 77.7% of respondents, as well as enhanced compliance and satisfaction among patients, reported by 76.8%. Major barriers identified included lack of technological infrastructure (84.8%), data privacy concerns (84.8%), and regulatory uncertainty (76.8%). While DCTs have advantages, regulatory uncertainties and infrastructure challenges remain barriers for their widespread adoption and implementation in India. We need targeted strategies in digital infrastructure, regulatory reforms, capacity building, and stakeholder engagement to address these challenges and facilitate broader adoption.

**Keywords:** Adoption, Clinical Research, Decentralized Clinical Trials, DCTs, Implementation, India, Perceived Barriers, Regulatory Challenges.

### Introduction

The traditional approach of clinical trials, which mostly depends on centralized study locations and site visits, has historically been regarded as the gold standard in clinical research [1]. This methodology has logistical problems, such as geographical constraints, increased expenses, and participant burden, which may impact recruitment, retention, and

overall trial efficacy [2, 3]. In the past few years, demand for decentralized clinical trials (DCTs) has surged as a novel alternative to conventional methodologies. DCTs use digital technology and remote methodologies, including telemedicine, electronic informed consent, wearable devices, and home health visits, to facilitate greater interaction between

clinical research and participants, therefore improving access and convenience [4].

The global COVID-19 outbreak sped up the acceptance of decentralized models by showing the shortcomings of site-dependent studies and emphasizing the need for ongoing clinical research during public health crises. [5]. The U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), among others, have issued guidelines to implement decentralized methods. These guidelines recognize that decentralized methods help in improving trial diversity and a patient-focused approach [6, 7].

Although the benefits of DCT, including enhanced patient participation, diversified geographic accessibility, and operational efficiencies are well established in developed countries, their implementation in developing countries such as India is still constrained [8].

India is the preferred destination for contract pharmaceuticals, attributed to its substantial treatment-naïve population, skilled people resources, technological expertise, regulatory adaptability, and evolving economic landscape [9]. In 2022, the virtual clinical trials market reported revenue of USD 127.0 million. By 2030, the digital clinical trials market is expected to bring in USD 219.5 million. The India virtual clinical trials market is expected to grow at a rate of 7.1% per year from 2023 to 2030. [10]. Thus, India's diverse healthcare infrastructure and extensive population present both unique challenges and significant opportunities for the implementation of DCTs. Factors such as regulatory uncertainty, infrastructural disparities, concerns regarding data privacy and trial integrity, and digital literacy level may influence stakeholders' readiness to transition to decentralized models. [11, 12].

We have limited data available on the perceptions of clinical researchers in India regarding the feasibility, benefits, and barriers of DCTs, despite its ever growing demand in this

field. It is important to understand these views so that educational, infrastructural, and governmental strategies can be adapted to promote widespread adoption. The aim of this study is to address this gap by conducting a cross-sectional survey among clinical researchers in India to evaluate their awareness, attitudes, and perceived challenges associated with the adoption and implementation of DCT.

The objectives of this study are as follows:

1. To assess the level of awareness and understanding of DCTs among clinical researchers in India.
2. To identify the perceived benefits and challenges in the adoption and implementation of DCTs.

## Methodology

The data was collected from clinical research professionals throughout India using a cross-sectional survey design. This design enables the compilation of data at a single point in time, thereby providing an overview of the current perspective, awareness, and attitudes of clinical researchers concerning DCTs.

The study targeted clinical researchers including professionals from hospitals, academic institutions, contract research organizations (CROs), pharmaceutical companies. Inclusion criteria encompassed professionals with a minimum of one year of experience in clinical research.

A questionnaire was developed using Google forms, comprising sections on demographics, awareness and experience with DCTs, perceived benefits and barriers, and outlook. The questionnaire included both closed and open-ended questions and were validated through a pilot test with 5 clinical research experts. Between Jan to Apr 2025, the survey was electronically disseminated through professional networks and mailing lists. A total of 112 verified responses were received.

The survey included a consent statement informing participants of the study's purpose, ensuring voluntary participation. All responses

were anonymized and used solely for research purpose. The study did not include patients and therefore was exempted from the ethics review.

Descriptive statistics were utilized to summarize the data. Inferential statistics, including chi-square tests, were employed to examine associations between demographic variables and perceptions. Qualitative responses were analyzed thematically.

## Results

The result has been written based on the study objectives and the responses obtained from the clinical researchers.

### Clinical Researchers in India were Evaluated for their Awareness and Understanding of Decentralized Clinical Trials

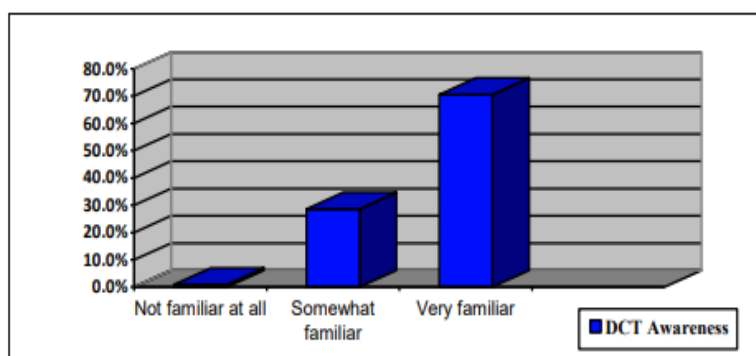
Table 1 presents the demographics of clinical researchers in India who have responded to the survey.

**Table 1.** Demographics of Clinical Researchers responded to the Questionnaire

Gender	Male respondent: 65.2%
	Female respondent: 34.8%
Age group	20-30 years: 6.3%
	30-45 years: 74.1%
	More than 45 years: 19.6%
Work experience	Upto 10 years: 11.6%
	11-25 years: 80.4%
	More than 25 years: 8%
Organizational details	Pharmaceutical/sponsor company: 37.5 %
	Service provider company: 54.5%
	University or research institute: 6.3%
	Other: 1.8% (consultants)
Organizational type	Large companies (more than 2500 employees): 71.4%
	Midsized companies (500 to 2500 employees): 10.7%
	Small sized companies (up to 500 employees): while 17.9%
Functional area	Clinical operations: 72.1%
	Executive management: 13.5%
	Data Management: 5.4%
	Quality Management: 2.7%
	Decentralized clinical trials: 1.8%
	Information technology: 0.9%
	Other: 4.5 % ( <i>includes Business development, record management, consultants</i> )

Clinical researchers had mean age of 39 years (Std. Deviation = 6.10), ranging from 32.9 to 45 years. Respondents had an average of 17.45 years of work experience in clinical research (Std. Deviation = 5.6), ranging from 12 to 23 years of work experience.

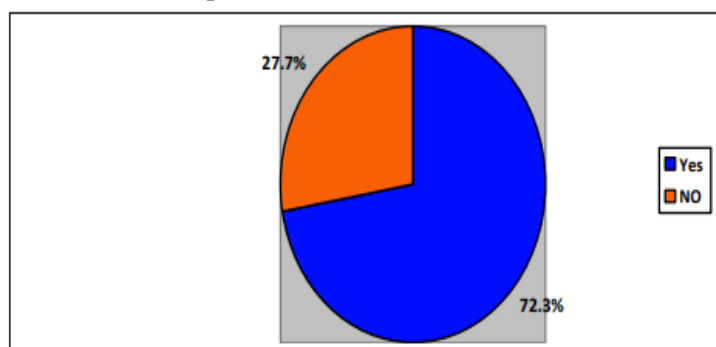
Based on the responses, 70.5% of the respondents were very familiar with the concept of decentralized clinical trials, while 28.6% were somewhat familiar and around 0.9% had never heard about DCT; as represented in Figure 1.



**Figure 1.** The Graph Represents Respondent's Awareness about the Decentralized Clinical Trial (DCT) Concept

72.3% (81 respondents) have participated in DCT prior and are well experienced in managing DCT while 27.7 % (31 respondents)

have still not been involved in conducting a DCT in India represented in Figure 2.



**Figure 2.** The Graph Represents the Respondents Involved vs Respondents with No Experience in Conducting a DCT in India

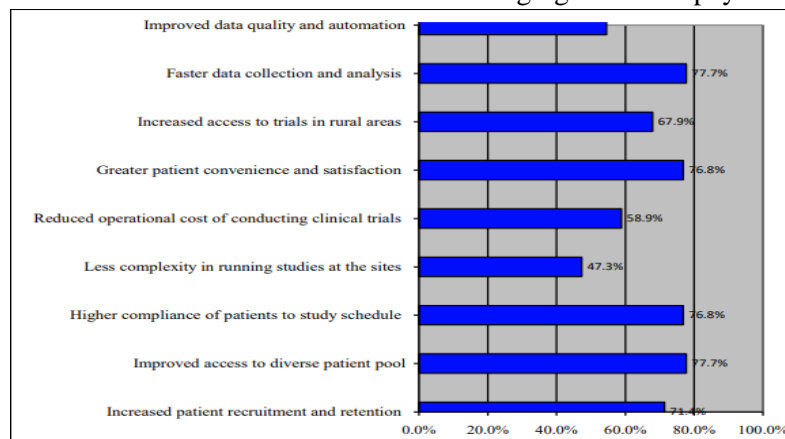
A chi-square test of independence was conducted to examine whether there is a relationship between work experience of clinical researchers and their involvement in conducting decentralized clinical trials (DCTs) in India. Participants were categorized into three groups based on years of experience: up to 10 years, 11–25 years, and more than 25 years. The test revealed a statistically significant association between the work experience and DCT involvement with a p value = 0.01. The group with 11–25 years of experience had the highest proportion of professionals involved in DCTs, followed by those with more than 25 years of experience. The group with up to 10 years of work experience showed the least involvement. This data shows that the correlation between years of experience and DCT participation is non-linear.

### The Assessment of Perceived Benefits and Challenges of DCT Implementation

The study of how DCT designs are used in different therapeutic areas showed that hybrid trial designs were more common than traditional trials or fully decentralized clinical trials. The survey responses for the perceived benefits of using DCTs are represented in the figure 3 below, which shows 77.7% believe that DCT has improved access to a diverse pool of suitable trial participants and faster data collection and analysis respectively. Additionally, higher patient compliance with visit and assessment schedules, along with stronger retention, was noted by 76.8%, aligning closely with the reported increase in patient convenience and satisfaction (76.8%). The ability of DCTs to increase patient recruitment and retention overall was

acknowledged by 71.4% of participants. Moreover, 67.9% emphasized that DCTs enable better access to clinical trials in rural or remote areas. From an operational perspective, 58.9% cited reduced costs associated with

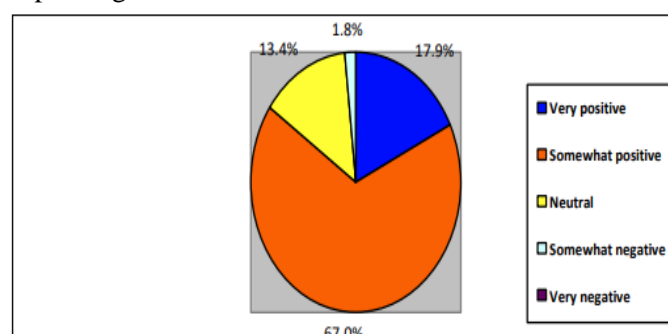
conducting clinical trials, while 54.5% noted improvements in data quality due to real-time access and automation. Finally, 47.3% observed a reduction in the complexity of managing studies at physical sites.



**Figure 3.** Perceived Benefits with DCT Adoption and Implementation

The responses were obtained to assess perceptions regarding the potential of DCTs to enhance trial timelines and efficiency in India. The results indicate a predominantly positive outlook among respondents represented in figure 4; 67% of respondents viewed DCTs as somewhat positive in improving trial timelines

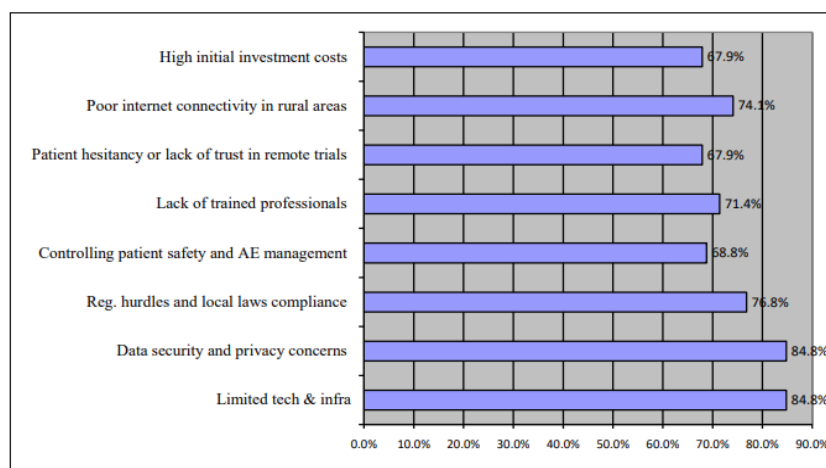
and efficiency. 17.9% rated the impact as very positive. 13.4% were neutral, indicating neither strong agreement nor disagreement. Only 1.8% expressed a somewhat negative view. Interestingly, none of the responder who answered said that the effect was very negative.



**Figure 4.** DCT's Potential in Improving Trial Timelines and Efficiency in India

The survey identified several key challenges perceived by stakeholders regarding the adoption and implementation of Decentralized Clinical Trials (DCTs) in India represented in Figure 5. The most frequently cited barriers were “limited technological infrastructure” and “data security and privacy concerns”, both reported by 84.8% of respondents. Other prominent concerns included “regulatory hurdles and compliance with local laws”

(76.8%), “poor internet connectivity in rural areas” (74.1%), “lack of trained professionals” (71.4%), and “controlling patient safety and adverse event management” (68.8%). Additionally, 67.9% of respondents noted “patient hesitancy or lack of trust in remote trials” and “high initial investment costs” were reported at 67.9%. A small proportion (1.8%) mentioned other unspecified challenges.



**Figure 5.** Perceived Challenges with DCT Adoption and Implementation

Based on the survey results, respondents have identified several critical steps necessary to promote the adoption of Decentralized Clinical Trials (DCTs) in India. The most emphasized measure was the need for enhancing regulatory support for DCTs, cited by 92% of participants. 89.3% of the respondents prioritized improving technological infrastructure in rural areas while 87.5% supported expanding patient education and awareness campaigns. Additionally, 81.3%

of respondents considered increasing training programs for professionals while 73.2% supported creating incentives for sponsors and institutions.

The survey had open-ended question for the respondents on the areas for the stakeholders (regulatory bodies, clinical researchers and technology providers) to better collaborate to promote the success of DCT in India. Table 2 presents a thematic analysis of the responses.

**Table 2.** Thematic Analysis on the Areas for the Stakeholders (Regulatory Bodies, Clinical Researchers and Technology Providers) to Better Collaborate to Promote the Success of DCT in India

Theme	Key Suggestions/Inputs	Frequency	Representative Quotes
Regulatory Guidelines & Support	Develop clear DCT-specific guidelines; simplify regulatory processes; approve e-consent and e-signatures.	High	“Proper guidelines need to be in place...” “Simplify regulatory approvals...”
Awareness & Education	Conduct awareness campaigns; train investigators and patients; organize DCT-specific conferences.	High	“Create awareness, incentivise companies...” “Education” “Conducting patient awareness programmes...”
Technology Enablement	Build user-friendly, affordable digital platforms; ensure compliance with Indian/global standards; integrate with initiatives like ABHA.	High	“Accessible digital platforms for remote monitoring...” “Patient data... ABHA can be game changer.”
Collaborative Efforts	Facilitate stakeholder collaboration; joint discussions; coordinated implementation efforts.	Moderate	“Collaborate approach for implementation” “Understanding each other's requirements...”

Pilot Studies/Phased Adoption	Start with pilot studies in low-risk areas; gradually scale based on outcomes.	Moderate	“Firstly Pilot Project should start...” “Phase IV trials can be early adopters.”
Incentives & Motivation	Incentivize DCT adoption by sponsors/CROs; demonstrate cost-effectiveness and quality benefits.	Moderate	“Incentivize companies supporting DCTs” “Demonstrating which activities... positively impacting time, cost, quality”
Patient-Centric Approach	Educate and support patients; ensure DCTs improve patient convenience and care.	Moderate	“Shift the mindset of the patient...” “If patients are able to get better treated without hassle...”
Infrastructure Readiness	Develop physical and digital infrastructure for remote trials; funding for setup.	Low	“Set-up of infrastructure...” “Funding & Infrastructure Development...”

A significant majority of respondents (87.4%) personally supported the adoption of Decentralized Clinical Trials (DCTs) in India. A small portion (5.4%) expressed opposition to DCT adoption, while 7.2% were unsure about their stance.

## Discussion

The present study explored the perceptions of clinical researchers in the adoption and implementation of the decentralized clinical trials (DCTs) in the Indian context. The gender distribution provided information about the diversity of perspectives on decentralized clinical trials (DCTs) in India. Most of the respondents belonged to the 30-45 years age group, indicating their significant involvement in the clinical research field.

### The Discussion is Based on the Objective of this Research

#### Clinical Researchers in India were Evaluated for their Awareness and Understanding of Decentralized Clinical Trials

The results indicate that professionals with moderate to high levels of experience (11–25

years) are more actively involved in conducting DCTs compared to those with lesser ( $\leq 10$  years) or very extensive ( $> 25$  years) experience. The relatively lower DCT participation among early-career professionals may reflect limited exposure to decentralized models, lack of training, or fewer opportunities to lead or participate in such trials. Interestingly, professionals with more than 25 years of experience also demonstrated lower involvement compared to the 11–25-years of work experience group. The findings may suggest a generational gap or resistance to adopting newer digital trial methodologies among the most experienced cohort [13]. In contrast, those in the 11–25 years range may represent a group with sufficient seniority to be involved in decision-making, while still being adaptive to evolving technologies and trial models like DCTs. This pattern demonstrates the need for strategic workforce development to enhance DCT awareness and skills across both early-career and senior professionals [14]. Ensuring continuous education and digital literacy in clinical research practice could help bridge the participation gap [15].

Most of the respondents in this study (72.1%) were actively engaged in clinical operations, serving in roles such as project managers, clinical research associates, and clinical trial assistants. This indicates that the perspectives captured largely reflect the experiences of professionals directly involved in the day-to-day execution and coordination of clinical trials, including protocol implementation, site management, and patient interaction. A smaller but significant portion (13.5%) of respondents held executive or senior management positions such as CEOs, directors, and associate directors. Their inclusion adds strategic insight into organizational priorities and high-level decision-making regarding DCT adoption. Additionally, a minority of respondents represented other functional domains such as advisory consultancy, business development, records management, and risk-based monitoring (RBM), grouped under the “Other” category. The diverse functional representation enhances the comprehensiveness of the findings, though it is important to note that operational perspectives dominate. This distribution likely influenced the emphasis placed on practical challenges—such as technological readiness, training, and patient engagement—over broader institutional or regulatory considerations. Understanding how perceptions vary by professional role can be valuable for tailoring DCT adoption strategies across different levels of the clinical research ecosystem [16].

The results indicate a high level of awareness about decentralized clinical trials (DCTs) among clinical research professionals in India, with 70.5% of respondents reporting that they were very familiar with the concept and an additional 28.6% being somewhat familiar. Only a negligible 0.9% had never heard of DCTs. This strong awareness suggests that DCTs have gained considerable visibility within the clinical research community, likely influenced by the global shift toward remote and technology-enabled trials in the aftermath

of the COVID-19 pandemic. The widespread familiarity is a promising sign for the future of DCT adoption, as it reflects a foundational understanding that can support further capacity building and implementation [17-19].

The study revealed that a substantial majority of respondents (72.3%) have previously participated in the conduct of decentralized clinical trials (DCTs) and possess hands-on experience in managing such trials. This high level of direct involvement indicates that DCTs are not just a theoretical concept among clinical researchers in India but are already being piloted or implemented in various capacities. This experiential exposure provides respondents with practical insights into the operational nuances, benefits, and challenges of DCTs—making their perspectives particularly valuable. In contrast, 27.7% of respondents reported no prior involvement in DCTs, suggesting that while adoption is growing, it has not yet become a standard practice across the board. The disparity in experience may reflect differences in institutional readiness, therapeutic focus, or geographic location. It also calls for broader dissemination of DCT models and more inclusive training initiatives to ensure that professionals across various sectors of the clinical research ecosystem are prepared to contribute to and benefit from the shift toward decentralized trial methodologies [20].

### **Assessment of Perceived Benefits and Challenges of DCT Implementation**

The predominance of hybrid designs in therapeutic areas indicates that sponsors are favouring a flexible approach that integrates traditional site visits with remote technologies [21]. Several key benefits were identified from the adoption of decentralized clinical trials (DCTs), as reported by the clinical research professionals. A significant majority highlighted improved access to a diverse pool of suitable trial participants, which enhances the representativeness and inclusiveness of



clinical research. Faster data collection and analysis were also reported as a major advantage by 77.7% of respondents, owing to the use of digital technologies and real-time data capture. Additionally, higher patient compliance with visit and assessment schedules, along with stronger retention, was noted by 76.8%, aligning closely with the reported increase in patient convenience and satisfaction (76.8%). The ability of DCTs to increase patient recruitment and retention overall was acknowledged by 71.4% of participants. Moreover, 67.9% emphasized that DCTs enable better access to clinical trials in rural or remote areas, thereby reducing geographical barriers to participation. From an operational perspective, 58.9% cited reduced costs associated with conducting clinical trials, while 54.5% noted improvements in data quality due to real-time access and automation. Finally, 47.3% observed a reduction in the complexity of managing studies at physical sites. Collectively, these findings indicate that DCTs offer substantial improvements in accessibility, efficiency, data quality, and patient engagement, supporting their growing adoption in the clinical research landscape in India [22, 23].

The findings suggest a largely optimistic perception of DCTs' potential to enhance trial timelines and efficiency in India. Most of the respondents viewed the impact as somewhat positive, while 17.9% rated it as very positive. This reflects strong overall support for the role of DCTs in improving operational aspects of clinical trials. The neutral stance of 13.4% indicates some reservation or a wait-and-see approach, whereas negative responses were minimal (1.8% somewhat negative, 0% very negative), underscoring broad acceptance and low resistance among stakeholders. These insights highlight a favourable environment for adopting DCT models to streamline clinical research in India.

The data clearly reflect that while the potential of DCTs is widely acknowledged,

several significant challenges hinder their full-scale adoption in India. The highest-rated concerns—technological infrastructure and data privacy—underscore the foundational limitations in digital readiness and the need for robust cybersecurity frameworks. These are critical, as DCTs rely heavily on digital tools for data capture, patient monitoring, and communication [24].

Regulatory compliance emerged as another major concern, emphasizing the complexity and ambiguity surrounding DCT-specific guidelines in the Indian context. Ensuring patient safety and managing adverse events remotely also remain prominent challenges, as traditional site-based trials typically offer more immediate oversight [25]. Issues such as lack of trained professionals and internet connectivity gaps in rural areas point toward disparities in resource distribution and digital literacy, especially in underserved regions. Moreover, patient hesitancy and high initial investment costs suggest both cultural and economic barriers that need to be addressed for broader acceptance.

These findings show that even though stakeholders are excited about DCTs, we need to take a comprehensive approach that includes updating the policies, improving the infrastructure, building skills and educating the users involved to ensure that they are successfully put in practise. [26- 28].

It would be critical to take measures to promote the DCT elements within the organization. The responses highlight a clear roadmap for advancing DCT implementation in India. The overwhelming consensus on enhancing regulatory support reflects an urgent demand for clearer guidelines, faster approvals, and alignment with international standards to facilitate the smoother conduct of decentralized trials. Regulatory clarity is foundational in boosting confidence among stakeholders and ensuring compliance. The call to improve technological infrastructure in rural areas underscores a persistent digital divide that

could hinder equitable participation in DCTs. Reliable internet connectivity and access to devices are essential to ensure that trials can reach and engage patients across diverse geographic regions. Patient education and awareness also emerged as a critical factor. Empowering patients with knowledge about the benefits, processes, and safety of DCTs can reduce hesitancy and build trust, especially in communities unfamiliar with digital healthcare interactions. Similarly, training clinical research professionals remains vital for ensuring that the workforce is equipped to manage decentralized protocols, technologies, and patient interactions effectively [29]. Lastly, incentivizing sponsors and institutions suggests the need for policy-driven or financial motivations to encourage early adoption, experimentation, and investment in DCT infrastructure. Indian government has launched Digital Health Incentive Scheme (DHIS) under the Ayushman Bharat Digital Mission (ABDM) that provides financial incentives to healthcare providers and digital solution companies to encourage the adoption of digital health records. Such, policy incentives are essential for institutions to invest in digital infrastructure, a core component of DCTs [30]. Without such incentives, institutions may be reluctant to transition from familiar traditional trial methods to newer, decentralized models.

In addition, thematic analysis demonstrates a consistent alignment between stakeholder concerns and established global best practices in the adoption of DCT. Regulatory reform is essential; without clear and unified guidelines, decentralized clinical trials (DCTs) face challenges in gaining traction in India. Awareness and training are critical, not just for investigators but also for patients who are the end beneficiaries of decentralized models. The technology landscape in India exhibits potential; however, the integration with local frameworks and the assurance of user-friendliness are crucial factors. Designing pilot studies and evaluating trial-specific DCT

feasibility cooperatively will help to build trust across the industry [31].

Moreover, the implementation of patient-centered approaches—focusing on comfort, accessibility, and data security is necessary to encourage long-term adoption [17].

Respondent who have personally advocated the adoption and implementation of DCT reflect a strong positive sentiment within the clinical research community regarding the potential of decentralized models. Such high levels of personal support are encouraging for policymakers and stakeholders, as they indicate readiness among professionals to adopt and engage with DCT models, provided that the systemic barriers can be addressed. Thus, these results are consistent with studies conducted in other developing countries, where researchers have expressed cautious optimism toward DCTs but emphasized regulatory and infrastructural challenges [32].

The findings underline the urgent need for a more robust regulatory framework to support DCTs in India. Regulatory authorities such as CDSCO [33] and ICMR must play a more proactive role in issuing guidance and supporting pilot programs. Additionally, training for clinical professionals is essential. The need for education on technological tools, ethical practices, and patient engagement in virtual settings is paramount. Improved infrastructure and targeted incentives for sponsors may further ease the transition to DCT models.

## Conclusion

The assessment of clinical researchers' perspectives reveals a generally positive outlook on the adoption and implementation of Decentralized Clinical Trials (DCTs) in India. Most respondents acknowledged the potential of DCTs to improve trial timelines and efficiency, indicating readiness for change within the research community. However, this optimism is tempered by substantial concerns

around infrastructure limitations, regulatory complexities, and operational challenges.

DCT participation is spread out evenly among various type of organization, showing that many different groups are adopting decentralized methods in Indian clinical research landscape.

This study found a statistically significant relationship between work experience and involvement in decentralized clinical trials in India. Professionals with 11–25 years of experience were most likely to be involved in DCTs, while those with  $\leq 10$  years and  $> 25$  years of experience had notably lower levels of participation. The results indicate that there should be specific efforts like training and support programs for both newer and experienced researchers, to increase their involvement with decentralized trial models and improve their use in clinical research environment in India.

Overall, the data suggests that while DCT adoption is underway, it is still in a transitional phase for most organizations, with moderate uptake being the norm. The persistent barriers point to the lack of high or very high adoption, indicating the need for broader and deeper integration. Moving forward, success in scaling DCT implementation will likely depend on factors such as leadership commitment, technology investment, regulatory clarity, training and awareness and cross-functional collaboration. We can expect a gradual shift toward higher adoption levels as confidence increases and early learnings become more shared.

To ensure the success of DCTs in India, a multi-directional strategy is required. The path forward includes:

1. Issuing robust regulatory guidelines tailored for Indian settings.

2. Launching national awareness and training initiatives for stakeholders.
3. Developing cost-effective, compliant digital tools integrated with national healthcare programs.
4. Implementing small-scale pilots to gather data and refine approaches.
5. Encouraging collaborative frameworks among regulators, pharmaceuticals, CROs, research institutes and technology partners.
6. Ensuring patient education and engagement is central to all DCT strategies.

In general, DCTs have potential to change clinical research in India, but to be successful, we need to tackle these challenges by investing in digital tools, regulatory reforms, improving skills and collaborating with the stakeholders.

This study is limited by its sample size and the use of self-reported data, which may be subject to bias. Furthermore, perceptions may evolve rapidly as DCT-related policies and technologies continue to develop.

Future research should focus on patient perspectives and real-world DCT case studies in India to evaluate feasibility and outcomes. Longitudinal studies assessing the impact of policy changes or pilot programs could also offer valuable insights. Additionally, exploring the views of regulators and institutional leaders would help identify additional barriers and accelerators of adoption.

## **Conflict of Interest**

The author(s) declare no potential conflict of interest with respect to the research, authorship and or publication of this article.

## **Acknowledgements**

The author is grateful to all the respondents who candidly answered the survey for the fulfilment of this research.

## References

- [1]. Friedman, L. M., Furberg, C. D., & DeMets, D. L., 2010, Introduction to clinical trials. In: Fundamentals of Clinical Trials. *Springer, New York, NY*, [https://doi.org/10.1007/978-1-4419-1586-3\\_1](https://doi.org/10.1007/978-1-4419-1586-3_1)
- [2]. Inan, O. T., Tenaerts, P., Prindiville, S. A. *et al.*, 2020, Digitizing clinical trials. *npj Digital Medicine*, 3, 101, <https://doi.org/10.1038/s41746-020-0302-y>
- [3]. Kadam, R. A., Borde, S. U., Madas, S. A. *et al.*, 2016, Challenges in recruitment and retention of clinical trial subjects. *Perspectives in Clinical Research*, 7(3), 137–143, <https://doi.org/10.4103/2229-3485.184820>
- [4]. Izmailova, E. S., Wagner, J. A., & Perakslis, E. D., 2020, Wearable devices in clinical trials: hype and hypothesis. *Clinical Pharmacology & Therapeutics*, 108(3), 513–515, <https://doi.org/10.1002/cpt.1853>
- [5]. U.S. Food and Drug Administration (FDA), 2020, Conduct of clinical trials of medical products during the COVID-19 public health emergency: Guidance for industry, investigators, and institutional review boards, <https://www.fda.gov/media/136238/download>
- [6]. U.S. Food and Drug Administration (FDA), 2023, Decentralized clinical trials for drugs, biological products, and devices: Guidance for industry, investigators, and other stakeholders, Decentralized Clinical Trials for Drugs, Biological Products, and Devices
- [7]. European Medicines Agency (EMA), 2023, Guideline on computerised systems and electronic data in clinical trials. <https://www.ema.europa.eu>
- [8]. Thiers, F., Sinskey, A. & Berndt, E., 2008, Trends in the globalization of clinical trials. *Nature Reviews Drug Discovery* 7, 13–14, <https://doi.org/10.1038/nrd2441>
- [9]. Maiti, R., Raghavendra, R., 2007, Clinical trials in India. *Pharmacological Research*; Volume 56, Issue 1, July, Pages 1–10, <https://doi.org/10.1016/j.phrs.2007.02.004>.
- [10]. Horizon Grand View Research; India Virtual Clinical Trials Market Size & Outlook, Date of access: 21/05/2025. <https://www.grandviewresearch.com/horizon/outlook/virtual-clinical-trials-market/india?>
- [11]. Bhattacharya, A., 2023, How decentralized clinical trials (DCTs) can revolutionize clinical trial in India? *Pharma Mirror*, Date of access: 21/05/2025, <https://www.pharmamirror.com>
- [12]. Devasenapathy, N., 2023, Decentralized clinical trials: Overcoming challenges, embracing opportunities. *The George Institute for Global Health*, <https://www.georgeinstitute.org>
- [13]. Kuek, A., Hakkennes, S., 2019. Healthcare staff digital literacy levels and their attitudes towards information systems. *Health Informatics Journal*, 26(1):592–612, <https://pubmed.ncbi.nlm.nih.gov/30983476/>
- [14]. Navarro-Martínez, O., Igual-García, J., & Traver-Salcedo, V., 2023, Bridging the educational gap in terms of digital competences between healthcare institutions' demands and professionals' needs. *BMC Nurs* 22, 144, <https://doi.org/10.1186/s12912-023-01284-y>
- [15]. Ferreira, J. C., Elvas, L. B., Correia, R., *et al.*, 2025, Empowering Health Professionals with Digital Skills to Improve Patient Care and Daily Workflows. *Healthcare*, 13(3), 329. <https://doi.org/10.3390/healthcare13030329>
- [16]. Kehoe, L., Calvert, S.B., Hallinan, Z., *et al.*, 2024, Adoption of Decentralization: Are Our Perceptions Holding Us Back? *Ther Innov Regul Sci*. <https://doi.org/10.1007/s43441-024-00636-3>
- [17]. Narasimhan S., 2023, Decentralized Clinical Trials -Systematic Review of Methods, Awareness, and Inclusiveness in Clinical Research, *Texila International Journal*, <https://www.texilajournal.com/academic-research/article/2382-decentralized-clinical-trials>
- [18]. ACRP Citiprogram, 2023, Decentralized Clinical Trials in a Post-Pandemic Era, 11 September, Date of access: 21/05/2025, <https://acrpnet.org/2023/09/11/decentralized-clinical-trials-in-a-post-pandemic-era>
- [19]. Vyas S., 2023, The rise of India as a hub for clinical trials: Factors, regulations & opportunities. *Pharmabiz*, 13 December, Date of access: 21/05/2025, <https://www.pharmabiz.com/NewsDetails.aspx?aid=165120&sid=9>

- [20]. ACRP, 2022, Delivering on the Promise of Decentralized Trials: Unexpected Perspectives from Clinical Research Professionals, Nov 2022 Date of access: 21/05/2025, <https://acrpnnet.org/delivering-on-the-promise-of-decentralized-trials-unexpected-perspectives-from-clinical-research-professionals>
- [21]. Pharmaceutical technology, 2024, How hybrid models and tech are shaping the future of clinical research; 5 November, Date of access: 21/05/2025, <https://www.clinicaltrialsarena.com/sponsored/how-hybrid-models-and-tech-are-shaping-the-future-of-clinical-research/>
- [22]. Gao F., Solomon M., *et al.*, 2021. Why Decentralized Clinical Trials Are the Way of the Future. *Applied Clinical Trials*, <https://www.appliedclinicaltrialsonline.com/view/why-decentralized-clinical-trials-are-the-way-of-the-future>
- [23]. Cliniexperts Research., 2023, What are Decentralized Clinical Trials (DCT) in India? 14 Sep, Date of access: 21/05/2025, <https://medium.com/clinexperts-research/what-are-decentralized-clinical-trials-dct-in-india-60b708535ad>
- [24]. Inampudi, S., Rajkumar, E., Gopi, A., *et al.*, 2024, Barriers to implementation of digital transformation in the Indian health sector: a systematic review. *Humanities and social sciences communication* 11, 632, <https://doi.org/10.1057/s41599-024-03081-7>
- [25]. Rasheed, S. H., 2024, Ensuring safety and monitoring adverse events in clinical trials: Challenges and innovations. *World Journal of Biology Pharmacy and Health Sciences*, 20(01), 454–457, <https://doi.org/10.30574/wjbphs.2024.20.1.0798>
- [26]. Jain D., 2023, Regulation of Digital Healthcare in India: Ethical and Legal Challenges. *Healthcare (Basel)*. Mar 21;11(6):911, doi: 10.3390/healthcare11060911. PMID: 36981568; PMCID: PMC10048681.
- [27]. Narayan, A., Bhushan, I. & Schulman, K., 2024, India's evolving digital health strategy. *npj Digit. Med.* 7, 284, <https://doi.org/10.1038/s41746-024-01279-2>
- [28]. Rajendran, R. U., Nayak, B. S., Siva, N., *et al.*, 2025, Stakeholder engagement in healthcare research in India - A systematic review. *Health Res Policy Syst.* May 15;23(1):57, doi: 10.1186/s12961-025-01341-9. PMID: 40375276; PMCID: PMC12080155.
- [29]. Freel, S. A., Snyder, D. C., Bastarache, K., *et al.*, 2023, Now is the time to fix the clinical research workforce crisis. *Clinical Trials.*, 20(5):457-462, doi:10.1177/17407745231177885
- [30]. Medical Buyer, 2024, India launches incentive scheme to boost digital health record adoption. Medical Buyer. Date of access: 21/05/2025, <https://www.medicalbuyer.co.in/india-launches-incentive-scheme-to-boost-digital-health-record-adoption/>
- [31]. Mantri, M., Sunder, G., & Kadam, S., 2024, A perspective on digital health platform design and its implementation at national level. *Frontiers in Digital Health*, 6, 1260855, <https://doi.org/10.3389/fdgth.2024.1260855>.
- [32]. Smith, Z., Getz, K., 2024, Examining the Association Between DCT Solutions Use and Participant Diversity in Clinical Trials. *Ther Innov Regul Sci.* May 11. doi: 10.1007/s43441-024-00659-w. Epub ahead of print. PMID: 38734837.
- [33]. Bhatt, A., & Joshi, A., 2023, Clinical Trials in India: Regulation and Oversight by Central Drugs Standard Control Organization. *Bhatt & Joshi Associates*. Date of access: 21/05/2025, <https://bhattandjoshiassociates.com/clinical-trials-in-india-regulation-and-oversight-by-central-drugs-standard-control-organization/>