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# Exploring the Perception of Clinical Researchers on the use and Importance of Decentralized Clinical Trial Elements in India

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***Abstract***

*This study aims to explore the perceptions of clinical researchers in India regarding the use and importance of decentralized clinical trial (DCT) elements and to identify associated organizational and therapeutic area-specific trends. A cross-sectional questionnaire-based survey was conducted among 112 clinical research professionals across various organizational types, including sponsor companies, contract research organizations (CROs), and academic institutions. Data was analyzed to assess the extent of DCT elements importance for its adoption and implementation in the organization based on the drug development pipeline. A statistical test was used to examine the association between organizational type and DCT elements adoption levels. The findings revealed a growing inclination toward hybrid trial models, with 78.6% of respondents indicating partial decentralization within their organizations. Only 11.6% of respondents reported a fully decentralized trial, highlighting regulatory, infrastructural, and operational constraints. A significant association was found between organizational type and DCT adoption ($p = 0.045$), suggesting that service providers and sponsor companies differ in their strategic approaches. Adoption patterns varied across therapeutic areas, with hybrid models dominating in complex conditions such as oncology and cardiovascular diseases and fully decentralized trials more common in dermatology and infectious diseases. Key enabling technologies included electronic signatures, remote source data verification, and AI-driven analytics, while infrastructure-heavy components like direct-to-patient delivery were less prioritized. DCT element adoption in India remains moderate and is primarily characterized by hybrid models. Service providers are emerging as key enablers of digital transformation, but regulatory ambiguity, gaps in digital infrastructure, and limited organizational readiness hinder broader implementation. Tailored policies, capacity-building initiatives, and therapeutic-specific strategies are essential for accelerating DCT integration.*

***Keywords:*** *Clinical Research, Decentralized Clinical Trials, DCT Elements, Hybrid Trials, India, Organizational Adoption, Therapeutic Area.*

## Introduction

The clinical research industry has revolutionized with the increasing adoption and implementation of decentralized clinical trials (DCTs), which aim to use the remote elements and digital health technologies that could reduce or eliminate the patient's visit physically to the study site [1]. COVID-19 pandemic acted as a catalyst to develop and adopt this innovative trial design to meet the need for patient recruitment, patient centricity and improving trial efficiency [2]. DCT design could be 'fully decentralized clinical trials', where all activities occur outside a traditional site like electronic informed consent (eConsent), home healthcare visits, teleconsultations, mobile health applications, and wearable sensor, that are considerably recognized for their potential to make the clinical trials more inclusive and accessible [3,

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4] The patients may engage in trial-related activities in their residences or at local healthcare establishments. Remote data collection is an essential component of decentralized trials. Other design, is the 'hybrid decentralized clinical trials' or 'partial decentralized trial' that uses the combination of conventional and remote components especially on-site visits for the study assessment, in person consent or e-Consent, electronic patient reported outcomes (e-PRO), telemedicine. It has been shown that hybrid trial design maximized remote methods [5].

In a recent study conducted in 2022, data was extracted from ClinicalTrials.gov and the clinical trials implemented the four components of DCT namely: telemedicine, home healthcare (HHC), direct-to-patient (DTP), and Internet of Healthcare Things (IoHTs)/Internet of Medical Things (IoMTs) and these components were defined as follows [6, 7]:

1. Telemedicine: The evaluation of study participant could be conducted through video or phone interactions with healthcare practitioners.
2. Home healthcare (HHC): A nurse or healthcare provider provides healthcare services including medication administration and collection of blood samples, at the study participant's residence.
3. Direct-to-patient (DTP): Investigational medicinal products can be delivered and administered in an at-home setting or other study-related materials can be dispensed to the participant without visiting the trial site location.
4. Internet of Healthcare Things (IoHTs)/Internet of Medical Things (IoMTs): Application of IoMT/IoHT namely:
    - Remote healthcare monitoring means checking a study participant's health while they are at home or somewhere outside a hospital or clinic, using technology. These devices collect health data and can be transferred to the Investigator,
    - Ambient Assisted living means using smart technology to help older people or people with health problems live safely and independently at home. It uses tools like sensors, smart devices, cameras or emergency buttons or health monitors to detect any unusual activity, remind patient to take their medicines or in case of emergencies alert the patient's caretaker.
    - Healthcare solutions with smartphones and wearable devices can be used to help monitor and manage health.

Other DCT elements like use of digital media for patient recruitment and retention, virtually conducting pre-selection visits or doing remote source data verification and monitoring. Additionally, electronic consenting, use of electronic signatures, completion for questionnaires electronically are also considered component of DCT.

While countries like the United States and members of the European Union have witnessed accelerated integration of DCT elements into mainstream research, adoption in developing countries, including India, has been slower and more fragmented [8, 9]. India's large population and diverse geography, infrastructure, and digital literacy provide both distinct opportunities and challenges for the implementation of DCTs. The capacity of DCTs to overcome these barriers and access underrepresented population is particularly relevant in India's rural and semi-urban areas [10]. However, regulatory uncertainties, infrastructural limitations, and a lack of standardized frameworks pose significant barriers to widespread DCT elements adoption [11, 12].

Despite growing interest, there remains limited empirical evidence on how Indian clinical researchers perceive the use and importance of DCT elements. Understanding their perspectives is essential, as these

stakeholders play a pivotal role in designing, managing, and overseeing trials. This study seeks to fill this gap by exploring the perception among clinical researchers in India regarding adoption and implementation of DCT elements.

## Methodology

A questionnaire was developed using quantitative cross-sectional design to collect the data from clinical researchers in India to explore their perception on the use and importance of decentralized clinical trial (DCT) elements.

The cross-sectional survey design enables the compilation of data at a single point in time [13].

The study population comprised of industry-affiliated personnel involved in the planning, conduct, or oversight of clinical trials.

The developed questionnaire focused on the DCT uptake trend in the organization with type of DCT design and elements used with their importance. The questionnaire was pilot-tested with 5 clinical researchers to ensure clarity, relevance, and reliability. Minor modifications were made based on their feedback. Then, the questionnaire was disseminated using google forms to around 450 clinical professionals through the professional platforms during the January to April 2025. Of which, 112 responded to the survey on time giving their valuable input. This sample size target is acceptable to meet the statistical reliability.

Participation was voluntary and the questionnaire 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 organization type and DCT trends in their organization.

## Results

A total of 112 clinical researchers from India participated in the survey. Among the respondents, 37.5% were employed by pharmaceutical or sponsor companies, 54.5% by service provider organizations, 6.3% by universities or research institutes, and 1.8% worked independently as consultants. Regarding organizational size, 71.4% of the participants were affiliated with large companies (more than 2,500 employees), 10.7% with midsized companies (500 to 2,500 employees), and 17.9% with small companies (up to 500 employees).

Following the COVID-19 pandemic, there has been a noticeable shift in trial conduct practices among clinical research organizations in India. As illustrated in Figure 1, 78.6% of respondents reported that their organizations now prefer a hybrid approach, combining conventional and decentralized clinical trial (DCT) elements. Additionally, 11.6% indicated full implementation of decentralized components and digital technologies in their trial operations. In contrast, 9.8% of the respondents stated that their organizations continue to rely solely on conventional methods for conducting clinical trials.

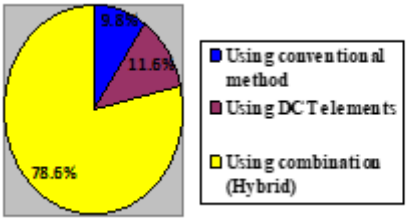


**Figure 1.** Post-pandemic, organization's preference of clinical trial design selection

When asked about the trend in decentralized clinical trials (DCT) over the past year, most respondents (56.8%) indicated that there had been no significant change, with an uptake of 'about the same.' However, 32.4% reported a moderate increase in the adoption of DCT elements, while a smaller proportion observed a significant increase (2.7%). On the other hand, 4.5% noted a significant decrease, and 3.6% reported a moderate decrease in DCT adoption within their organizations. Figure 2 shows a graphical representation of the DCT adoption and implementation trend in the organization during the last year.

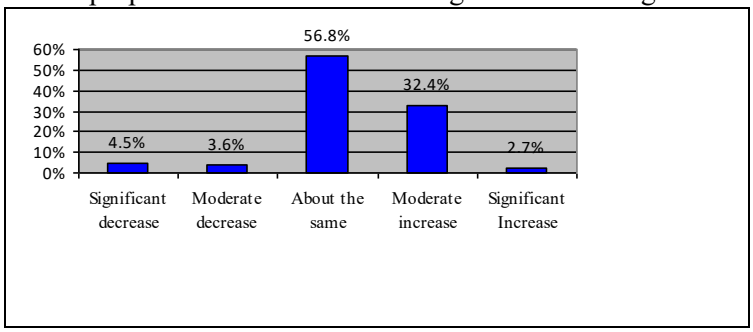


**Figure 2.** The Graphical Representation on Organization's Trend in Last Year in DCT Adoption and Implementation

Respondents reported involvement in a diverse range of therapeutic areas within the current drug development pipeline in the organization. Oncology emerged as the most common area, with 68.8% of clinical researchers indicating active trials in this domain. This domain was followed by metabolic and endocrine disorders (59.8%), cardiovascular diseases (58.0%), immunology & rheumatology (57.1%), and gastroenterology (51.8%). Respiratory (48.2%) and hematology (37.5%) were also frequently cited areas of ongoing research. Table 1 below represents the therapeutic indications from the ongoing trials.

**Table 1.** Respondent's Involvement in Ongoing Trials in the Various Therapeutic Indication

| **Therapeutic indication** | **Ongoing trials** |
|---|---|
| Biosimilar | 31.3% |
| Oncology | 68.8% |
| Metabolic & Endocrine | 59.8% |
| Cardiovascular | 58.0% |
| Immunology and Rheumatology | 57.1% |
| Gastroenterology | 51.8% |
| Respiratory | 48.2% |
| Hematology | 37.5% |
| Infectious diseases | 31.3% |
| Neurology | 26.8% |
| Dermatology | 25.0% |
| Vaccine development | 18.8% |
| Rare diseases | 15.2% |
| Nephrology | 14.3% |
| Women's health | 12.5% |
| Urology | 10.7% |
| Cell & Gene therapy | 9.8% |
| Critical Care | 9.8% |

| | |
|---|---|
| Pediatrics | 9.8% |
| Other | 2.7% |

A small proportion of respondents (2.7%) reported working in other therapeutic areas, which included ophthalmology, wound care, and herbal and traditional medicine.

The analysis of decentralized clinical trial (DCT) design adoption across various therapeutic areas revealed a clear preference for hybrid trial models, which combine both conventional and decentralized elements. Hybrid designs were predominant across most therapeutic indications, accounting for 84% of studies in cardiovascular, 81.1% in immunology and rheumatology, 77.2% in hematology, 77.3% in respiratory and 75% in gastroenterology and women's health.

Fully decentralized trials reported reasonably higher adoption in dermatology (30.6%), infectious diseases (22%), metabolic and endocrine disorders (21.8%), and the "other" category (30.8%). In contrast, traditional on-site trial designs were still the most common in certain areas like critical care (62.5%), pediatrics (46.9%), rare diseases (39.4%), and oncology/cell and gene therapy (34.5%).

The uptake of fully decentralized trials remained particularly low in certain domains, with only 3.6% in oncology, 5.3% in hematology, 6.1% in rare diseases, and 6.3% in critical care, indicating the continued dependence on traditional or hybrid approaches in these complex therapeutic areas. Table 2 summarizes the detailed breakdown in percentage of the preferred DCT design adoption and implementation according to the therapeutic indication.

**Table 2.** Preferred DCT Design Adoption and Implementation based on the Therapeutic Indication

| **Therapeutic Indication** | **Traditional (On-site trial)** | **Hybrid** | **Fully decentralized clinical trial** |
|---|---|---|---|
| Biosimilar | 12.5% | 70.8% | 16.7% |
| Cardiovascular | 8% | 84% | 8% |
| Cell and gene therapy | 34.5% | 55.2% | 10.3% |
| Critical Care | 62.5% | 31.3% | 6.3% |
| Dermatology | 12.2% | 57.1% | 30.6% |
| Gastroenterology | 11.8% | 75% | 13.2% |
| Hematology | 17.5% | 77.2% | 5.3% |
| Immunology and Rheumatology | 12.2% | 81.1% | 6.8% |
| Infectious diseases | 10% | 68% | 22% |
| Metabolic and Endocrine | 5.1% | 73.1% | 21.8% |
| Nephrology | 11.1% | 69.4% | 19.4% |
| Neurology | 18% | 72% | 10% |
| Oncology | 34.5% | 61.9% | 3.6% |
| Pediatrics | 46.9% | 40.6% | 12.5% |
| Rare diseases | 39.4% | 54.5% | 6.1% |
| Respiratory | 9.1% | 77.3% | 13.6% |
| Urology | 18.8% | 65.6% | 15.6% |
| Vaccine development | 21.6% | 56.8% | 21.6% |
| Women's health | 12.5% | 75% | 12.5% |
| Other | 30.8% | 38.5% | 30.8% |

Survey answers, shown in Figure 3, showed difference in how organization adopted specific components of DCT. Remote Source Data Verification (SDV) and remote data monitoring emerged as the most widely adopted elements, reported by 84.8% of respondents. This conclusion was followed by high adoption rates for electronic signatures (76.8%), electronic questionnaires (75%), and the use of digital media for patient recruitment (71.4%). Similarly, virtual pre-site selection visits (68.8%) and the implementation of AI/ML solutions for data analysis (66.1%) also reflected strong organizational uptake. In contrast, moderate levels of adoption were observed for e-Consent (54.5%), telemedicine (50%), Internet of Healthcare/Medical Things (IoHTs/IoMTs) (50%), and home healthcare services (46.4%). Notably, the direct-to-patient (DTP) delivery of investigational products demonstrated the lowest level of adoption, reported by only 30.4% of respondents. These findings highlight that the integration of DCT elements is not consistent, with technology-based and monitoring features being used more often than innovations that focus on patient needs.

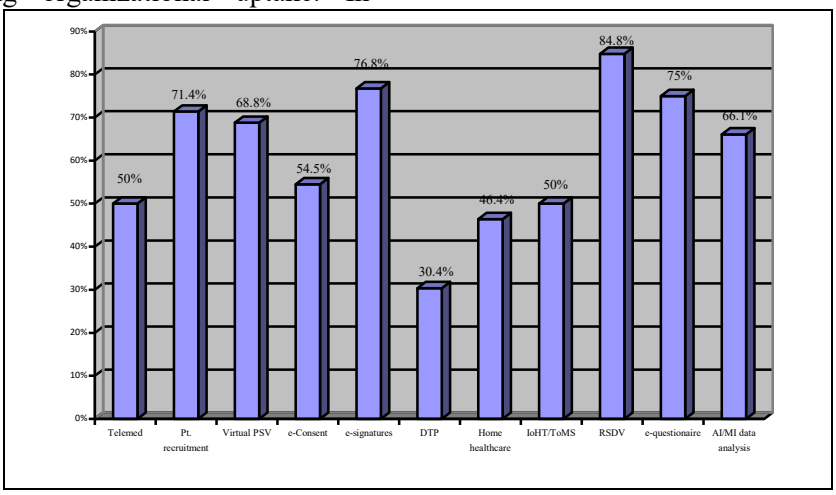


**Figure 3.** Uptake of DCT Elements by the Organization

The survey results shown in Figure 4 reveal that 66.1% of respondents said their organizations have a moderate level of using decentralized clinical trial (DCT) elements. A smaller proportion (14.3%) reported low adoption, while 8 % cited extremely low adoption. Interestingly, 6.3% of respondents expressed uncertainty regarding the extent of DCT adoption in their organization. Only 5.4% reported very high adoption, and notably, no respondents indicated high adoption. These results suggest that while DCT element implementation is underway in many organizations, it remains at a moderate level, with limited instances of full-scale or high-level integration.

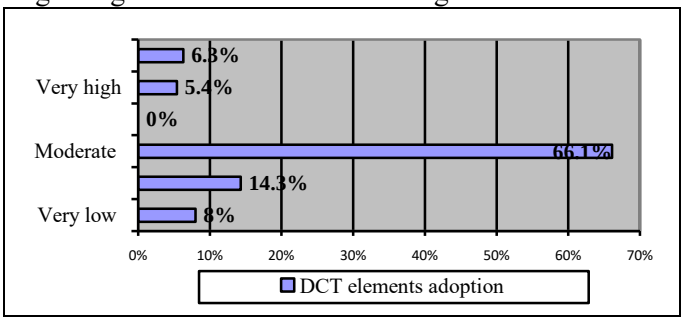


**Figure 4.** Organizational Adoption of DCT Elements

**Association between Type of Organization and Level of DCT Elements Adoption**

A chi-square test was used to examine the relationship between the type of organization and its adoption of decentralized clinical trial (DCT) elements. The analysis compared pharmaceutical/sponsor companies and service provider companies, as shown in Table 3. The results showed a meaningful link between the type of organization and how much they use decentralized clinical trial (DCT) elements (p-value = 0.045), meaning that pharmaceutical/sponsor companies and service provider companies differ in their adoption of DCT elements.

**Table 3.** Evaluation of Association between Organization Type & Level of Adoption of DCT Elements

| Organization | Very low adoption of DCT elements | Low adoption of DCT elements | Moderate adoption of DCT elements | Very high adoption of DCT elements |
|---|---|---|---|---|
| Pharmaceutical/ sponsor company | 2 | 6 | 33 | 1 |
| Service provider company | 6 | 7 | 37 | 5 |

Among pharmaceutical/sponsor companies, most respondents reported moderate adoption (n = 33), with fewer indicating low (n = 6) or very low adoption (n = 2), and only one respondent citing very high adoption. In contrast, service provider companies also showed a predominance of moderate adoption (n = 37) but had a relatively higher number of respondents reporting very high adoption (n = 5) and very low adoption (n = 6) compared to their pharmaceutical counterparts.

These findings suggest that service provider companies might show a wider range of DCT adoption levels, possibly due to different ways they operate or their different roles in running trials, while pharmaceutical/sponsor companies seem to be more focused on moderate levels of adoption.

**Importance of DCT Elements:**

Survey responses showed that people in India have different views on how important various decentralized clinical trial (DCT) technologies are, as shown in Table 4. Electronic Signatures were seen as the most important technology, with 54.5% of respondents saying it was ‘Totally Important’ and 31.3% saying it was ‘Important’. Other technologies that were also seen as very important included AI/ML solutions for data analysis at 36.6% & 39.3%, electronic questionnaires at 25.9% & 49.1%, remote source data verification (SDV) and remote data monitoring at 26.8% & 42.9%, smartphones and wearable devices at 21.4% & 50.9%, and virtual pre-site selection visits at 22.3% & 42.9%. Electronic signatures emerged as the most impactful technology, with 54.5% of respondents rating it as ‘Totally Important’ and 31.3% rating it as ‘Important.’ Other technologies perceived as highly important and important included AI/ML solutions for data analysis at 36.6% & 39.3%, electronic questionnaires at 25.9% & 49.1%, remote source data verification (SDV) and remote data monitoring at 26.8% & 42.9%, smartphones and wearable devices at 21.4% & 50.9%, and virtual pre-site selection visits at 22.3% & 42.9%, respectively. These findings indicate strong recognition of the value of digital and data-driven tools in enhancing trial efficiency and data quality. Patient recruitment through digital media at 45.5% was also regarded as important, reflecting a positive outlook on digital tools that support trial planning and participant engagement. Technologies such as

telemedicine, home healthcare, and e-consent were viewed as moderately to highly important.

Conversely, direct-to-patient (DTP) delivery and ambient assisted living received relatively lower perceived importance, with only 10.7% and 8%, respectively, rating them as 'totally important.' This means that while basic and data-focused DCT technologies are seen as valuable, the more complicated logistical and infrastructure-related aspects might be considered less important or harder to put into practice in the Indian clinical research environment.

**Table 4.** Perceived Level of Importance for Different DCT Elements in India

| DCT Element | Not Important | Slightly important | Moderately Important | Important | Totally Important |
|---|---|---|---|---|---|
| Telemedicine | 3.6% | 13.4% | 21.4% | 30.4% | 8.9% |
| Patient recruitment through digital media | 6.3% | 6.3% | 22.3% | 45.5% | 13.4% |
| Virtual pre-selection visits | 1.8% | 12.5% | 12.5% | 42.9% | 22.3% |
| Electronic consent (e-Consent) | 4.5% | 14.3% | 21.4% | 28.6% | 13.4% |
| Electronic signature (e-signature) | 1.8% | 4.5% | 5.4% | 31.3% | 54.5% |
| Direct to patient (DTP) | 3.6% | 8.9% | 17.9% | 25.9% | 10.7% |
| Home healthcare monitoring | 3.6% | 6.3% | 22.3% | 30.4% | 14.3% |
| Ambient assisted living | 5.4% | 8.9% | 9.8% | 19.6% | 8% |
| Smart phones, wearable devices | 1.8% | 6.3% | 8.9% | 50.9% | 21.4% |
| Remote source data verification (SDV) and remote monitoring | 3.6% | 3.6% | 19.6% | 42.9% | 26.8% |
| Electronic questionnaires | 2.7% | 2.7% | 17.9% | 49.1% | 25.9% |
| AI and ML solutions for data analysis | 1.8% | 2.7% | 9.8% | 39.3% | 36.6% |

## Discussion

The findings of this research study offer helpful perspectives on the evolving landscape of decentralized clinical trials (DCTs) conducted in India. A total of 112 clinical researchers participated in the survey, representing a diverse cross-section of the Indian clinical research industry. Most respondents were affiliated with service provider organizations (54.5%) and large-scale companies with more than 2,500 employees (71.4%). This distribution suggests that the perspectives captured in this study largely reflect operational realities. A noteworthy observation from the study is the growing preference for hybrid models of trial conduct. A substantial 78.6% of respondents reported that their organizations had adopted a hybrid approach, combining conventional and decentralized elements. This pattern is consistent globally that pandemic served as an opportunity for digital transformation in clinical research [14]. Hybrid trials offer flexibility to maintain patient safety and data quality while improving accessibility and retention through the selective use of digital tools [15, 16].

Only 11.6% of respondents indicated that their organizations had implemented fully decentralized approaches. This finding reflects that the regulatory frameworks, infrastructure readiness, and stakeholder confidence are still developing. Despite the global momentum, the complete adoption of DCTs in India may be

hindered by concerns such as data privacy, digital literacy, and variability in technological infrastructure across urban and rural settings [17].

In contrast, 9.8% of participants reported continued reliance on conventional trial methodologies. This segment likely includes organizations that operate in niche therapeutic areas, have limited digital capabilities, or cater to populations less suited for remote interventions. It also highlights the persistent challenges of change management and the need for organizational readiness, training, and policy support for broader DCT adoption [18].

The data from this study further supports the argument that hybrid models are becoming mainstream in India, even though the complete transition to fully decentralized trials remains limited.

The distribution of respondents across different types and sizes of organizations offers an important contextual lens for interpreting these findings. Larger organizations, particularly multinational service providers and sponsors, may have better access to technological infrastructure and global protocols, thereby facilitating faster adoption of DCT practices. In contrast, smaller organizations or academic institutions may face more pronounced financial or logistical barriers to implementing such innovations [19, 20].

When examining recent trends, 56.8% of respondents reported no significant change in DCT adoption over the past year, while 32.4% noted a moderate increase. These findings suggest a plateau in momentum following the initial acceleration during the pandemic, possibly due to operational, technical, or logistical challenges [21]. A small proportion also reported decreases in DCT adoption, underscoring the variability in organizational capabilities and commitment to digital transformation.

This study highlights the varying patterns of decentralized clinical trial (DCT) adoption across therapeutic areas within India's clinical research landscape. Oncology emerged as the most actively pursued therapeutic domain, with 68.8% of respondents involved in trials related to cancer, aligning with global trends in oncology R&D investments. Other prominent areas included metabolic and endocrine disorders, cardiovascular diseases, and immunology—reflecting India's growing burden of non-communicable diseases and the corresponding research priorities [22].

The analysis reveals a distinct preference for hybrid trial designs across most therapeutic domains. This model was especially dominant in cardiovascular (84%), immunology and rheumatology (81.1%), and hematology (77.2%) trials. Using hybrid models shows they can keep the trial's quality while adding features that focus on the patient, like remote monitoring, online consultations, and collecting data electronically. These designs are particularly useful in managing chronic conditions that require long-term follow-up but benefit from reduced patient burden [23-28].

Notably, fully decentralized trials were more commonly implemented in dermatology (30.6%), infectious diseases (22%), and metabolic and endocrine disorders (21.8%). These areas are more suited for remote and digital trial models due to less intensive monitoring requirements and the feasibility of virtual assessments [29-32]. Conversely, adoption of fully decentralized models remained minimal in difficult and high-risk areas such as oncology (3.6%), hematology (5.3%), and critical care (6.3%). These therapeutic areas often involve specialized interventions, complex logistics, and frequent in-person assessments, necessitating continued reliance on conventional or hybrid trial structures [33-35].

Additionally, areas like pediatrics and rare diseases had low adoption of DCTs, probably because of ethical issues, challenges with informed consent and difficulties in using digital tools for children [36]. These findings demonstrate the importance of tailored DCT

strategies that align with the clinical and operational realities of each therapeutic area.

Overall, while hybrid trial designs are becoming popular across therapeutic domains in India, the full decentralization of trials is still limited by disease complexity, trial requirements, and regulatory factors. This nuanced adoption pattern shows that Indian research organizations are being pratical toward integrating DCTs based on feasibility and therapeutic context.

The survey results reveal that the implementation of decentralized clinical trial (DCT) elements in India is presently moderate, with 66.1% of respondents indicating this level of adoption within their organizations. Only a small minority reported very high adoption (5.4%), and notably, no respondents cited high adoption, underscoring a cautious and incremental integration of DCT components in clinical research operations. These findings reflect the transitional stage of DCT deployment in India; organizations are engaging with DCT models, but full-scale integration remains limited. This moderate uptake may be attributed to a variety of factors, including regulatory ambiguity, infrastructural limitations, and concerns over data security and reliability in remote settings [37]. The uncertainty expressed by 6.3% of respondents further highlights the evolving nature of organizational strategies and the potential lack of internal clarity on DCT initiatives. Similar transitional trends have been observed globally, where hybrid models serve as a bridge toward fully decentralized frameworks [15].

Additionally, the low percentage of respondents reporting low (14.3%) or extremely low (8%) adoption suggests that while DCTs are being considered or partially implemented, there are still challenges for their wider use. Organizational readiness, digital literacy, and availability of validated technologies remain critical enablers for broader DCT integration [17].

Overall, these findings emphasize that while DCT adoption is progressing in India, it is largely characterized by moderate engagement, with substantial scope for policy support, infrastructure strengthening, and stakeholder training to facilitate higher levels of adoption.

The result from the Chi-Square Test of Independence showed a significant association between the type of organization and the level of adoption of decentralized clinical trial (DCT) elements in India ($p = 0.045$). This indicates that organizational affiliation—whether a pharmaceutical/sponsor company or a service provider plays a role in shaping the extent to which DCT elements are integrated into clinical research practices. While both organizational types showed a predominance of moderate adoption, service providers exhibited a broader range of adoption levels, including a relatively higher incidence of both very high and very low adoption. This variability may reflect the diverse operational scopes and strategic priorities of service providers, who often manage multiple trial functions such as remote monitoring, digital data capture, and site support, across different sponsor organizations. Pharmaceutical and sponsor companies, in contrast, showed a more concentrated trend towards moderate adoption. This observation may suggest a cautious, centralized approach to DCT implementation, possibly driven by regulatory uncertainty, the need for internal capacity building, or the prioritization of traditional trial paradigms. This aligns with earlier research highlighting that sponsor organizations tend to proceed with incremental adoption of DCT elements to ensure compliance and data integrity, particularly in emerging markets like India, where infrastructure and regulatory frameworks are still evolving [38].

Survey responses further underscored the perceived importance of specific DCT technologies. Electronic Signatures were rated as the most critical, with 85.8% of respondents marking them as either "Totally Important" or

"Important." This finding supports previous literature suggesting that technologies ensuring regulatory compliance and documentation integrity are among the first to be adopted in DCT strategies. Similarly, AI/ML-driven analytics, remote source data verification (SDV), and electronic questionnaires were seen as vital tools to improve trial efficiency and data accuracy, reinforcing findings from other studies on digital transformation in clinical research [39, 40].

Interestingly, more complex logistical elements such as Direct-to-Patient (DTP) delivery and Ambient Assisted Living were ranked lower in importance. This likely reflects infrastructural challenges, logistical constraints, and concerns around cost-effectiveness and scalability in the Indian context [7]. These findings highlight a practical prioritization among Indian clinical researchers on favoring scalable, digital-first tools over infrastructure-heavy solutions.

Overall, these results suggest a growing but cautious adoption of DCTs in India, with an emphasis on regulatory-compliant digital tools and data management solutions. The wider use of DCTs in India may show that service providers are the key players in helping to connect sponsor with decentralized methodologies. For wider DCT implementation in India, tailored strategies that address infrastructural readiness, regulatory clarity, and stakeholder-specific barriers are essential.

## Conclusion

This study provides valuable information about how decentralized clinical trials (DCT) are being adopted in India, based on views from 112 clinical researchers from various organizational settings. The results show a noticeable move towards hybrid trial models, with 78.6% of respondents saying they use a mix of traditional and decentralized methods in their research. This trend reflects a pragmatic approach wherein flexibility, patient accessibility, and operational continuity are prioritized, particularly in the post-pandemic research landscape.

Despite global momentum, fully decentralized trials remain underutilized in India, with only 11.6% reporting their adoption. This finding suggests that significant structural and regulatory challenges persist, including concerns around data privacy, digital literacy, and uneven technological infrastructure. The association between organizational type and DCT adoption levels, as evidenced by a statistically significant result, further underscores that strategic direction, resource availability, and operational roles influence the extent of DCT implementation.

Therapeutic areas also play a critical role in shaping DCT strategies. Hybrid models were especially prevalent in trials related to chronic and complex conditions such as cardiovascular diseases, immunology, and oncology, where patient safety and long-term follow-up are critical. Conversely, fully decentralized approaches were more feasible in therapeutic areas like dermatology and infectious diseases, which require less intensive in-person monitoring. Indian sponsor and service provider companies must promote the use of DCT technologies for their clinical trials at the pilot level to evaluate their feasibility.

Technological adoption was similarly varied, with strong emphasis placed on regulatory-compliant digital tools such as electronic signatures and remote data verification, while more logistically demanding solutions like direct-to-patient (DTP) delivery were ranked lower in importance. This prioritization reflects a strategic focus on scalable and cost-effective innovations, particularly among service providers who often serve as operational intermediaries.

Overall, the study underscores a cautious yet progressive transition toward decentralized methodologies in India, led predominantly by hybrid models. To facilitate broader and more effective DCT element adoption, there is a need for policy support, infrastructure development,

stakeholder training, and therapeutic area-specific frameworks. These efforts will be essential to overcoming existing barriers and ensuring that the benefits of decentralization, such as increased trial efficiency, participant reach, and data integrity can be fully realized within the Indian clinical research ecosystem.

The limitation of this study is that self-reported survey data may influence how the responses are interpreted. The sample is varied, but it may not completely reflect every stakeholder in the Indian clinical research ecosystem. The survey's cross-sectional design restricts its ability to identify trends.

Future research should aim at longitudinal studies to evaluate hybrid and decentralized models long-term effects on trial results, patient participation, and operational efficiency, longitudinal studies are needed.

## Conflict of Interest

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

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## References

[1]. U.S. Food & Drug Administration (FDA) guidance document on conducting clinical trials with decentralized elements., 2024 Sep. https://www.fda.gov/media/167696/download

[2]. Banks, M., 2021, In the wake of COVID-19, decentralized clinical trials move to center stage. *PNAS,* November 17, 118 (47) e2119097118, https://doi.org/10.1073/pnas.2119097118

[3]. Stern, A. D., Trusheim, M., 2024, Transformation of the clinical trial enterprise: lessons learned from the COVID-19 pandemic: final report. *Decentralized clinical trials and digital health technologies*. Feb 9, https://www.ncbi.nlm.nih.gov/books/NBK609002/

[4]. Alemayehu, D., Hemmings, R., Natarajan, K., *et al*., 2022, Perspectives on Virtual (Remote) Clinical Trials as the "New Normal" to Accelerate Drug Development. *Clinical Pharmacology Therapeutics,* Feb, 111(2):373-381. doi: 10.1002/cpt.2248. Epub 2021 Apr 19. PMID: 33792920.

[5]. Hanley, D. F., Jr. Bernard, G. R., *et al*., 2023, Decentralized clinical trials in the trial innovation network: Value, strategies, and lessons learned. *Journal of Clinical Translational Science* Jul 25. 7(1): e170. doi: 10.1017/cts.2023.597. PMID: 37654775; PMCID: PMC10465321.

[6]. Chodankar, D., Raval, T., K., Jeyaraj, J., 2024, The role of remote data capture, wearables, and digital biomarkers in decentralized clinical trials. *Perspectives in Clinical Research* 15(1): p 38-41, Jan–Mar| DOI: 10.4103/picr.picr_219_22

[7]. Sato, T., Mizumoto, S., Ota, M., *et al*., 2023, Implementation status and consideration for the globalisation of decentralised clinical trials: A cross-sectional analysis of clinical trial databases. *BMJ Open,* 13(10), e074334. https://doi.org/10.1136/bmjopen-2023-074334.

[8]. GlobalData, 2022, Clinical trials – The movement towards decentralized clinical trials. October 10 Date of access: 25/05/2025. https://www.globaldata.com/store/report/decentralized-clinical-trials-insight-analysis/

[9]. Wang, M., Huang, K., *et al*., 2025. Health workers' adoption of digital health technology in low- and middle-income countries: a systematic review and meta-analysis. *Bulletin World Health Organization;* 103:126–135F| doi: http://dx.doi.org/10.2471/BLT.24.292157

[10]. 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 Communications* 11, 632 https://doi.org/10.1057/s41599-024-03081-7

[11]. Gupta, P., Rai, C., et al., 2023, A Comprehensive Roadmap for MedTech Innovations Uptake into the Public Healthcare System in India.

*Frontiers in Digital Health*. DOI: 10.3389/fdgth.2023.1268010

[12]. Valachis, A., Lindman, H., 2024, Lessons learned from an unsuccessful decentralized clinical trial in Oncology. *npj Digit. Med.* 7, 211, https://doi.org/10.1038/s41746-024-01214-5

[13]. Setia, M. S., 2016, Methodology series module 3: Cross-sectional studies. *Indian Journal of Dermatology,* 61(3), 261–264. https://doi.org/10.4103/0019-5154.182410

[14]. Leyens, L., Simkins, T., Horst, N. K., 2022, The COVID-19 pandemic as a catalyst for innovation: a regulatory framework to assess fit-for-purpose innovative approaches in clinical research. *Trials* 23, 833, https://doi.org/10.1186/s13063-022-06707-w

[15]. Lamberti, M. J., Smith Z., Dirks, A., *et al*., 2022, The Impact of Decentralized and Hybrid Trials on Sponsor and CRO Collaborations. *Applied clinical trials,* July 27. Date of access: 27/05/2025, https://www.appliedclinicaltrialsonline.com/view/the-impact-of-decentralized-and-hybrid-trials-on-sponsor-and-cro-collaborations

[16]. Sehrawat, O., Noseworthy, P., A., Siontis, K., C., *et al*., 2023, Data-Driven and Technology-Enabled Trial Innovations Toward Decentralization of Clinical Trials: *Opportunities and Considerations. Mayo Clinic Proceedings,* Volume 98, Issue 9, September, Pages 1404-1421, https://doi.org/10.1016/j.mayocp.2023.02.003

[17]. Apostolaros, M., Babaian, D., Corneli, A. *et al*., 2020, Legal, Regulatory, and Practical Issues to Consider When Adopting Decentralized Clinical Trials: recommendations from the clinical trials transformation initiative. *Ther Innov Regul Sci* 54, 779–787, https://doi.org/10.1007/s43441-019-00006-4

[18]. Izmailova, E., S., Ellis, R., Benko, C., 2020, Remote Monitoring in Clinical Trials During the COVID-19 Pandemic. *Clin Transl Sci*. Sep;13(5):838-841. doi: 10.1111/cts.12834. Epub 2020 Jul 8. PMID: 32526077; PMCID: PMC7307062.

[19]. Moogi, A., Kalyandurgamath, K., 2022, A Review of significance of Decentralized Clinical Trials in India and impact of Data Analytics in Clinical Data. Dec 11, YMER || ISSN: 0044-0477, https://ymerdigital.com/

[20]. DiMasi, J., A., Smith, Z., Oakley-Girvan, I., *et al*., 2023, Assessing the Financial Value of Decentralized Clinical Trials. *Ther Innov Regul Sci* 57, 209–219, https://doi.org/10.1007/s43441-022-00454-5

[21]. Izmailova, E., S., Wagner, J., A., Ammour, N., *et al*., 2020, Remote Digital Monitoring for Medical Product Development. *Clin Transl Sci.,* 23 July, https://doi.org/10.1111/cts.12851

[22]. Sabu, S., T., Venkatraman, S., Cherian, J., *et al*., 2024, A review of clinical trials registered in India from 2008 to 2022 to describe the first-in-human trials. *Perspectives in Clinical Research* 15(1): p 18-23, DOI: 10.4103/picr.picr_124_23

[23]. Pelter, M., N., Quer, G., Pandit, J., 2023, Remote Monitoring in Cardiovascular Diseases. *Curr Cardiovasc Risk Rep* 17, 177–184, https://doi.org/10.1007/s12170-023-00726-1

[24]. Mayfield, J., J., Chatterjee, N., A., Noseworthy, P., A., et al., 2021, Implementation of a fully remote randomized clinical trial with cardiac monitoring. *Commun Med* 1, 62. https://doi.org/10.1038/s43856-021-00052-w

[25]. Portnoy, J., M., Pandya, A., Waller, M., *et al*., 2020, Telemedicine and emerging technologies for health care in allergy/immunology. *Journal of Allergy and Clinical Immunology,* Volume 145, Issue 2, February, Pages 445-454, https://doi.org/10.1016/j.jaci.2019.12.903

[26]. Bernard, L., Valsecchi, V., Mura, T., *et al*., 2022, Management of patients with rheumatoid arthritis by telemedicine: connected monitoring. A randomized controlled trial. *Joint Bone Spine,* Volume 89, Issue 5, October, 105368, https://doi.org/10.1016/j.jbspin.2022.105368

[27]. Samanta, J., Mishra, D., 2022, Future of Digital Health and Precision Medicine in Rheumatology Practice in India. *Indian Journal of Rheumatology* 17(Suppl 3):p S426-S430, December. | DOI: 10.4103/injr.injr_146_22

[28]. Shah, A., C., O'Dwyer, L., C., Badawy, S., M., 2021, Telemedicine in Malignant and Nonmalignant Hematology: Systematic Review of Pediatric and Adult Studies. *JMIR Mhealth Uhealth*, 9(7):e29619,

doi: 10.2196/29619|PMID: 34255706|PMCID: 8299344

[29]. Ali, Z., Zibert, J., R., Thomsen, S., F., 2020, Virtual Clinical Trials: Perspectives in Dermatology. *Dermatology* 236 (4): 375–382, Volume 236, Issue 4, https://doi.org/10.1159/000506418

[30]. Vashisht, K., R., Sahu, P., Mandula, P., P., *et al*., 2024, Bridging gaps in pediatric dermatology via telemedicine: An analytical cross-sectional study on 961 children in resource-limited areas of North India using the e-Sanjeevani 2.0 platform. *Indian J Dermatol Venereol Leprol.* doi: 10.25259/IJDVL_1223_2024

[31]. Coombes, C., E., Gregory, M., E., 2019, The Current and Future Use of Telemedicine in Infectious Diseases Practice. *Curr Infect Dis* Rep 21, 41, https://doi.org/10.1007/s11908-019-0697-2

[32]. Anjana R., M., Pradeepa, R., Deepa, M., 2020, Acceptability and Utilization of Newer Technologies and Effects on Glycemic Control in Type 2 Diabetes: Lessons Learned from Lockdown. *Diabetes Technology & Therapeutics,* Vol. 22, No. 7, https://doi.org/10.1089/dia.2020.0240

[33]. Fu, S., Gerber, D., E., Beg, M., S., 2022, Decentralized Clinical Trials in Oncology: Are We Ready for a Virtual-First Paradigm? *J Clin Oncol. 2023 Jan* 10;41(2):181-185. doi: 10.1200/JCO.22.00358. Epub Aug 22. PMID: 35994691; PMCID: PMC9839231.

[34]. Adams, D., V., Long, S., Fleury, M., E., 2022, Association of Remote Technology Use and Other Decentralization Tools with Patient Likelihood to Enroll in Cancer Clinical Trials. *JAMA Netw*., 5(7): e2220053. doi:10.1001/jamanetworkopen.2022.20053

[35]. Bhalsod, D., Taksande, K., Paul, A., et al., 2025, Bridging the gap between ICU and home-based care: A review of wearable technologies and remote monitoring in critical care. *Multidisciplinary Reviews,* 8(8), 2025256. https://doi.org/10.31893/multirev.2025256

[36]. Dhengale, M., Nagrik, S., Bathe, H., *et al*., 2025, Challenges and Innovations in Conducting Clinical Trials in Rare and Orphan Diseases. *Int. J. Sci. R. Tech.,* 2025, 2 (5), 427-441. https://doi.org/10.5281/zenodo.15459246

[37]. Hanley, D., F., Bernard, G., R., Wilkins, C., H., *et al.*, 2023, Decentralized clinical trials in the trial innovation network: Value, strategies, and lessons learned. *Journal of Clinical and Translational Science.* 2023;7(1): e170. doi:10.1017/cts.2023.597

[38]. Bhatt, A., 2014, Clinical trials in India: Way forward. Perspectives in Clinical Research 5(2):p 53-54, Apr–June | DOI: 10.4103/2229-3485.128017

[39]. Cummins, M., R., Burr, J., Young, L., *et al*., 2023, Decentralized research technology use in multicenter clinical research studies based at U.S. academic research centers. *Journal of Clinical and Translational Science.,*7(1): e250. doi:10.1017/cts.2023.678

[40]. Krittanawong, C., Aydar, M., Virk, H., U., 2022, Artificial Intelligence-Powered Blockchains for Cardiovascular Medicine. *Canadian Journal of Cardiology,* Volume 38, Issue 2, February, Pages 185-195, https://doi.org/10.1016/j.cjca.2021.11.011