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Systematic Review

Decentralized clinical trials-balancing promise and pitfalls in modern research: a systematic review

Arghya Biswas[1], Jeroze Dalal[2]*

[1]Department of Clinical Research, Texila American University, Guyana, South America
[2]Global Medical Affairs, Chief Patient Organisation, GlaxoSmithKline Pharmaceuticals, Mumbai, Maharashtra, India

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***Correspondence:**
Dr. Jeroze Dalal,
E-mail: jeroze.x.dalal@gsk.com

ABSTRACT

Background: Traditional clinical trials often face limitations in participant diversity and accessibility due to geographic and logistical constraints. Decentralized clinical trials (DCTs) have emerged as a potential solution to address these challenges by leveraging digital and remote technologies. Despite their advantages, there remains a lack of comprehensive understanding regarding the opportunities and challenges associated with DCTs. This systematic review explores the opportunities and challenges of DCTs, providing insights into their implementation and impact on clinical research. The review analyses DCTs' effects on trial conduct and outcomes, offering recommendations for future design and execution.
Methods: A systematic literature review was conducted following PRISMA guidelines, searching major databases for studies published between 2018 and March 2024. The review analyzed 18 peer-reviewed articles, assessing risk of bias using an adapted Cochrane tool.
Results: The results highlighted that DCTs enhance participant engagement, improve accessibility and increase participant diversity, offering potential cost savings and improved trial efficiency. However, challenges such as ensuring data integrity, overcoming technological barriers and addressing regulatory compliance were also noted. The majority of the included studies demonstrated a low risk of bias across all domains, enhancing the reliability of these findings.
Conclusions: This review underscores DCTs' potential to transform clinical research by improving efficiency, accessibility and participant diversity. Successful implementation requires addressing technological, ethical and regulatory challenges. Future research should focus on standardized best practices, equity issues and comparative studies with traditional trials. These findings have significant implications for shaping future clinical trials.

Keywords: Decentralized clinical trials, Digital health technology, Patient-centric trials, Regulatory challenges, Trial accessibility

INTRODUCTION

A decentralized clinical trial (DCT) utilizes technology and processes to reduce or eliminate the need for participants to physically visit traditional research sites. Although DCTs were gaining traction before COVID-19, the pandemic significantly accelerated their adoption, with a nearly 55% increase in new trials incorporating DCT elements between 2020 and 2022 (tufts center for the study of drug development). Traditional clinical trials, which rely on site-based methodologies, face several challenges. These include geographical barriers that restricted participant pools to those near clinical sites.[1] They also suffer from a lack of diversity, leading to limited demographic representation in trial results.[2]

Participants often face significant burden due to regular site visits.[3,4] Additionally, these trials involve high costs and time-intensive processes.[5] There are also concerns about their long-term sustainability and scalability.[6] DCTs address these challenges by integrating digital technology, facilitating remote monitoring and data

collection and enabling remote study activities such as virtual recruitment and telemedicine visits.[7-10] They offer increased accessibility with broader geographic reach and flexibility while enhancing the frequency and accuracy of data gathering.[8,11,12] By reducing site visits, DCTs can improve participant recruitment and retention. However, challenges remain in regulatory compliance, data quality assurance and equitable technology access.

This systematic review provides a comprehensive analysis of the benefits and challenges of DCTs, offering a unique synthesis of current evidence across multiple themes including recruitment, efficiency, data quality and patient experience, thereby providing a holistic view of the DCT landscape to inform future research and implementation strategies.

The objectives of this review are to identify key DCT advantages in enhancing trial efficiency, participant experience and recruitment strategies; elucidate challenges and barriers for successful DCT implementation, including technological, regulatory and ethical considerations; analyze DCTs' impact on participant diversity, data quality and cost-effectiveness.

Additionally, the review aims to examine the role of technology integration in DCTs and its implications for trial design and methodology; and provide evidence-based recommendations for future DCT design, execution and regulatory frameworks. This review aims to guide researchers, clinicians and policymakers in optimizing DCT implementation for more effective and innovative clinical trials.

This review adheres to ethical standards, ensuring transparency and rigor in evidence synthesis, with no direct patient involvement.

METHODS

Search strategy

A systematic literature review was conducted in accordance with the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines. Sources included PubMed, Scopus, Web of Science, Springer, Cochrane and EMBASE. Search terms included "Decentralized Clinical Trial," "Remote Trial," "Virtual Trial," "patient experience," "diversity," "economic impact," "digital health," "data management," "regulatory aspects," and "real-world evidence".

Inclusion criteria

Study types

Original research articles, systematic reviews, qualitative studies, recommendation papers or perspective pieces providing substantial insights into DCTs.

Trial design

Studies reporting, discussing or evaluating decentralized methods in clinical trials.

Publication source

Peer-reviewed journals or scientific conference presentations.

Content focus

Studies addressing implementation, operational aspects, challenges or opportunities of DCTs, including but not limited to patient experience, diversity, financial value, digital health, data quality, regulatory considerations and real-world evidence generation.

Publication timeframe

Studies published was between 2018 and 2024.

Language

Studies published in English.

Exclusion criteria

Conventional trials

Studies focused on traditional trials without significant DCT elements.

Duplicates

Duplicate publications of the same study.

Irrelevant literature

Marketing reports, commentaries, viewpoints, editorials, letters to the editor and news articles.

Article screening process

A strict and systematic approach was applied for the screening of articles. The data obtained through the database search conducted in March 2024 (PubMed, Scopus, Springer, Web of Science, Cochrane Library and EMBASE) were uploaded into a reference manager to delete the duplicates.

Title and abstract were reviewed to determine whether the identified articles discuss DCTs. The full texts were evaluated for the prospects and issues of DCTs.

The systematic screening process ensured that only high-quality and relevant studies were included, making the analysis comprehensive.

Data extraction

A systematic data extraction form was used to ensure accuracy and reliability. Basic information collected from the selected papers included the author names, publication year, study type, sample population, intervention/aspect studied, comparison/control, outcome measures and findings.

Special emphasis was placed on extracting information from the articles regarding the implementation of DCTs, specifically focusing on the types of digital technologies used, the reported benefits, challenges encountered and overall outcomes. This methodical process of sifting and sorting allowed for the systematic compilation of relevant findings, highlighting the opportunities and challenges of DCTs.

Risk of bias assessment

Risk of bias was assessed using a modified Cochrane Risk of Bias 2 (RoB 2) tool, adapted to account for the observational and mixed-method nature of DCT studies. Five domains were evaluated: study design bias, missing data bias, outcome measurement bias, selective reporting bias and intervention bias.

RESULTS

Study selection and characteristics

The study selection process is illustrated in Figure 1 (PRISMA Flow Diagram). Our initial search yielded 2,559 records across six databases. After screening and applying exclusion criteria, 18 articles were included in the final review. Key observations from the selection process revealed that 1,021 records were excluded for various reasons, including reviews or meta-analyses without original data, non-peer-reviewed articles, studies with poor methodological quality, preliminary reports or studies with insufficient data. Many studies were excluded for not focusing specifically on DCTs or lacking sufficient data on challenges and opportunities. Additionally, some articles were excluded for lacking practical guidance on DCT implementation. The screening process involved reviewing 613 articles after title and abstract reading, with 107 full-text articles assessed for eligibility.

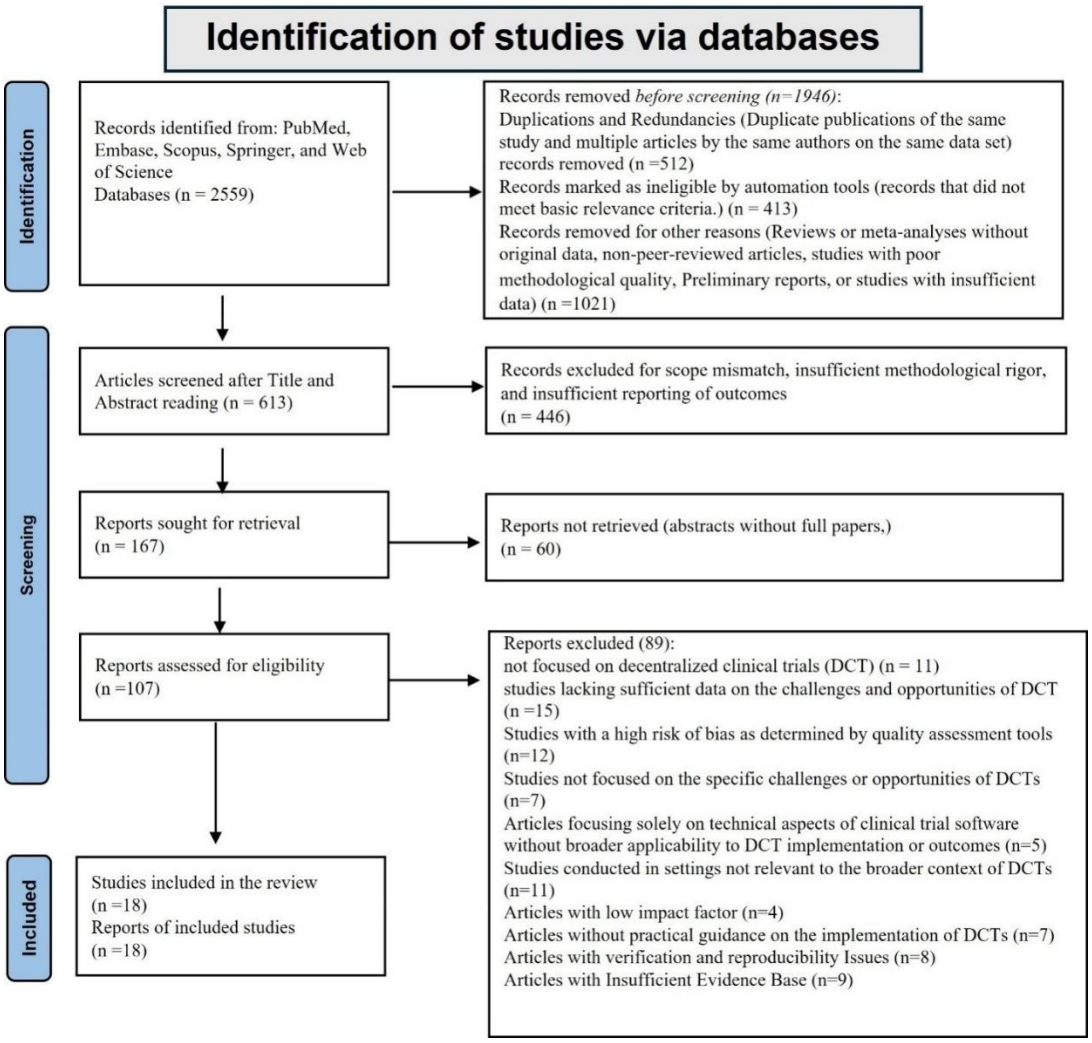

Figure 1: PRISMA flow diagram.

Table 1: Key themes, benefits and challenges of DCTs.

Theme	Benefits	Challenges	Key references
Recruitment and participation	Higher enrolment numbers, improved access for rural patients (26.7% from non-metropolitan areas), increased patient diversity	Only 5% of eligible patients participate in traditional trials	Sommer et al[25], Huh et al[19], Goodson et al[14]
Efficiency and cost-effectiveness	Increased expected net present value (eNPV, defined as the projected financial value of a drug) by $20M in phases II/III, reduced phase durations (≥10%)/≈3 months, screen failure rates decreased from 31.5% to 24.1% in phase II trials and from 29.9% to 20.1% in phase III trials, seven-fold return on investment (ROI) compared to traditional trials, cost reductions of $507,600 for phase II due to fewer amendments	Initial investment in technology and infrastructure	DiMasi et al[21], Harmon et al[17]
Data collection and quality	High completion rates for e-diaries (95.6%), 67.1% of bowel diary records completed on schedule, enhanced real-time safety monitoring	Data reliability concerns, logistical challenges in data collection across projects	Lau et al[23], Huh et al[19], Goodson et al[14], Hoban et al[20]
Patient experience and engagement	High satisfaction with digital tools, reduced burden of hospital visits, patients felt validated throughout their trial experience	Trust and communication challenges in remote settings	Sommer et al[25], Boxal et al[13], Coyle et al[18]
Technological adoption	Widespread use of electronic institutional review boards (eIRB), eSource, clinical trial management systems (CTMS), e-Signatures, electronic patient-reported outcomes (ePROs)	Less common use of wearables and online recruitment portals, technology usability issues, digital divide limitations	Cummins et al[22], Nebie et al[12], Goodson et al[14], Sehrawat et al[27],
Ethical and regulatory considerations	Clinical trials transformation initiative (CTTI) developed recommendations for DCTs, potential for more inclusive trials	Need for updated regulatory frameworks, addressing legal and ethical challenges	Apostolaros et al[26], De Jong et al[11], Petrini et al[7]
Real-world data and patient monitoring	Unique patient insights from natural environment, Enhanced real-time safety monitoring capabilities	Ensuring data quality in less controlled environments	Singh et al[15], Harmon et al[17], Goodson et al[14]

Methodological approaches of included studies

The 18 articles included in this review employed diverse methodological approaches. These encompassed qualitative methods such as interviews and case studies, quantitative techniques including clinical trials, data analysis and surveys, as well as literature reviews synthesizing existing research. Some studies utilized mixed methods, combining qualitative and quantitative approaches to provide a comprehensive analysis of DCTs.

Benefits and challenges of decentralized clinical trial

Our review identified several significant benefits and challenges associated with DCTs, as presented in Table 1. These findings encompass various aspects of DCTs, including recruitment and participation, efficiency and cost-effectiveness, data collection and quality, patient experience and engagement, technological adoption, ethical and regulatory considerations, real-world data and patient monitoring and cost implications. The table summarizes the key themes that emerged from our analysis of the 18 included articles, presenting benefits, challenges and key references for each theme.

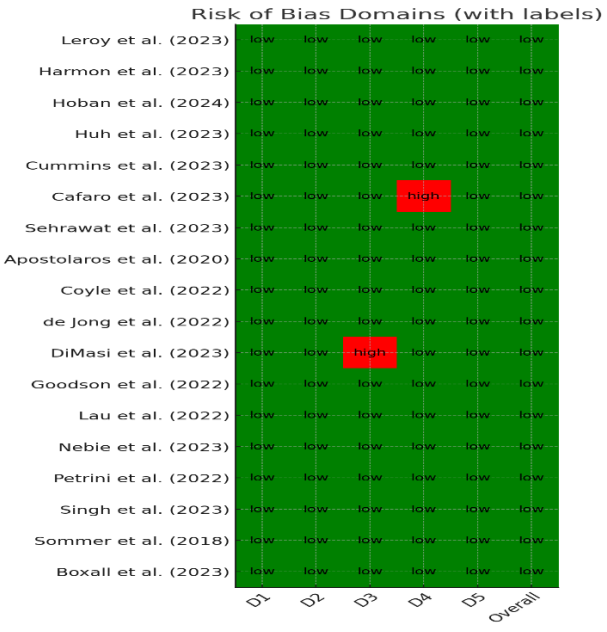

Figure 2: Summary of risk of bias.
Rows represent studies; columns represent domains (D1: Study Design, D2: Missing Data, D3: Outcome Measurement, D4: Selective Reporting, D5: Intervention) and overall risk. Green cells indicate low risk; red cells indicate high risk.

Risk of bias analysis results

As shown in Figure 2, most studies had a low risk of bias across all domains. Only two studies showed a high risk of bias in single domains: selections of reported results 24 and measurements of outcomes 21. This overall low risk of bias enhances the reliability of our findings regarding DCTs.

DISCUSSION

The findings from this systematic review reinforce both the advantages and challenges associated with DCTs. This discussion delves deeper into the observed key themes, analyzing their implications for the future of clinical trials and highlighting areas for further research and development.

Enhancing recruitment, participation and diversity

One of the primary advantages of DCTs is their potential to enhance accessibility and increase participant diversity. Cafaro et al and DiMasi et al, demonstrated that remote and semi-automated trial methods improve recruitment, especially among underrepresented populations.[16,21] Sommer et al, provided further support for this advantage, reporting significantly higher recruitment rates in the decentralized arm compared to the conventional arm. Goodson et al and Nebie et al, echoed this sentiment, discussing how DCTs address logistical barriers faced in traditional trials, particularly for individuals in rural or underserved areas.[12,14,25] This increased accessibility is further evidenced by Huh et al, who reported that 26.7% of their study participants were from non-metropolitan areas.[19] These findings are particularly significant given Goodson et al.'s observation that only 5% of eligible patients participate in traditional trials, suggesting DCTs could substantially increase participation rates.[14]

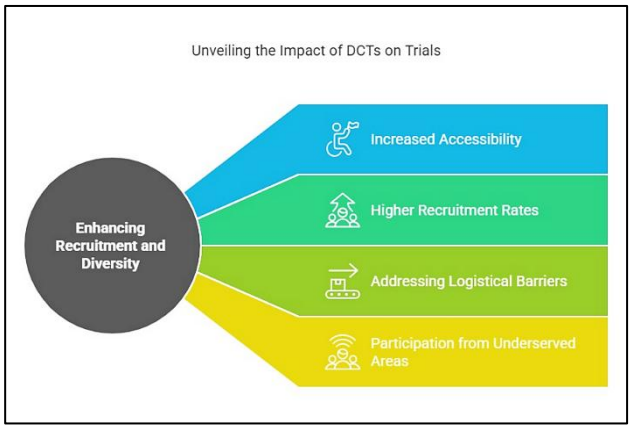

Figure 3: DCTs on recruitment and diversity: emphasizes improved accessibility and participation from underserved areas, based on 18 studies (2018–2024).

By reaching traditionally underserved populations, DCTs have the potential to make clinical trials more representative of diverse populations, potentially leading to more generalisable results and addressing long-standing issues of health disparities in medical research.

Improving patient experience and engagement

DCTs significantly reduce participant burden, which is another substantial benefit. Betcheva et al and DiMasi et al, emphasized that minimizing the need for in-person visits improves participant satisfaction and retention.[8,21] Sommer et al, reported high patient satisfaction with eICF and eDiary, demonstrating the positive impact of these digital tools on participant experience.[25] Boxal et al, found that participants felt validated throughout their trial experience, while Coyle et al, emphasized the importance of trust and communication in remote settings.[13,18] By leveraging digital technologies, DCTs ease logistical constraints and enhance overall trial participation. This reduction in burden could lead to higher retention rates and more complete data collection, potentially improving the overall quality and reliability of clinical trial results. Future research should explore how this reduced burden translates to long-term participant engagement, especially in studies requiring extended follow-up periods.

Leveraging real-world data and patient monitoring

Singh et al and Harmon et al, highlighted the potential of DCTs to provide unique patient insights from natural environments and enhance real-time safety monitoring capabilities.[15,17] Singh et al, also emphasized the need for sustainable DCT frameworks to support this accelerated therapeutic development.[15] These advantages could lead to more ecologically valid data and improved patient safety. However, they also noted challenges in ensuring data quality in less controlled environments, suggesting a need for robust remote monitoring protocols. The development of such protocols presents an opportunity for innovation in clinical trial design and execution.

Improving efficiency and cost-effectiveness

DCTs offer broader financial benefits beyond direct cost savings. As DiMasi et al, highlighted, DCTs increase resource efficiency and promote long-term sustainability in trial management.[21] Harmon et al, further noted that digital technology enhances clinical trial efficiency and participation, while also providing impactful real-world data.[17] Their study reported an increased eNPV by $20 million per drug in phases II and III and reduced phase II and III durations by at least 10%. Furthermore, they reported a specific cost reduction of $507,600 for phase II trials due to fewer amendments and decreased screen failure rates from 31.5% to 24.1% in phase II trials. While the initial investment in technology and infrastructure for DCTs can be substantial, the long-term cost benefits are significant. DiMasi et al, reported that the return on investment (ROI) for DCTs is seven-fold

based on eNPV increments.[21] These financial advantages make DCTs a more viable option for clinical research, especially in resource-limited settings. The potential for cost savings could lead to more trials being conducted, making clinical trials more accessible to a wider range of researchers and organizations. This could accelerate the pace of medical research and drug development, potentially democratize the drug development process and lead to a more diverse range of treatments being investigated. Despite these advantages, several challenges associated with DCTs must be addressed.

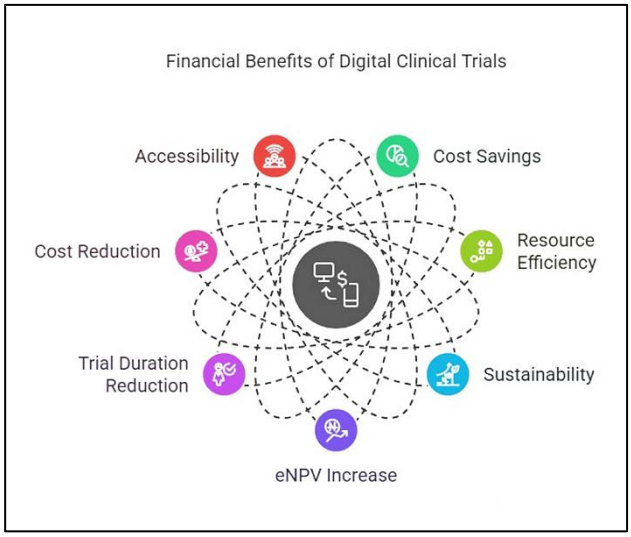

Figure 4: Financial benefits of DCTs: Accessibility, cost savings, resource efficiency, sustainability, cost reduction, trial duration reduction and eNPV increase, based on 18 studies (2018–2024).

Technological challenges and the digital divide

The digital divide presents a significant challenge, particularly in terms of accessibility. Sehrawat et al and Nebie et al, pointed out that DCTs may inadvertently exclude participants who lack access to the necessary technology or stable internet connections.[12,27] This limitation could hinder the inclusiveness of DCTs, particularly in low-resource settings. Cummins et al, reported widespread adoption of eIRB, eSource and clinical trial management systems, but noted that wearables and online recruitment portals were less commonly used, indicating uneven technological adoption across DCT applications.[22] Nebie et al, also highlighted technology usability issues, suggesting a need for innovative solutions to ensure equitable access.[12]

Addressing this challenge will require innovative solutions, such as providing technology to participants or developing low-tech alternatives for data collection in certain settings. Future research should focus on strategies to bridge this digital divide to ensure that DCTs truly enhance, rather than limit, participant diversity.

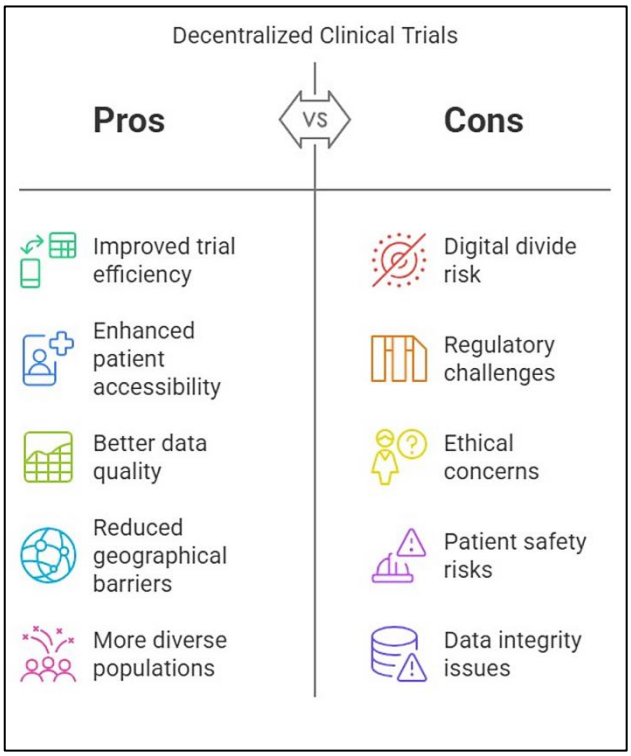

Figure 5: DCTs: Benefits include improved efficiency and diversity; challenges include the digital divide and regulatory hurdles, based on 18 studies (2018–2024).

Enhancing data collection and quality

Data integrity remains a primary concern, as de Jong et al, noted.[11] Ensuring the accuracy and reliability of remotely collected data requires robust cyber security protocols.[15] Without these measures, DCTs risk compromise the validity of their outcomes. On the positive side, Goodson et al, highlighted enhanced real-time safety monitoring capabilities in DCTs, which could contribute to improved data integrity.[14] Encouragingly, Lau et al, reported high completion rates (95.6%) for e-diaries, while Huh et al, found that 67.1% of bowel diary records were completed on schedule.[19,23]

Similarly, Cafaro et al, reported high adherence rates and data completeness in their DCT, further demonstrating the effectiveness of remote methods in improving data quality.[16] These findings suggest that well-designed digital tools can yield reliable data collection in decentralized settings. However, Hoban et al, highlighted logistical challenges in data collection across projects, indicating a need for standardized protocols.[20] Developing standardized protocols for DCTs is crucial. These protocols should cover data collection, transmission and storage. Such standardization will help maintain data integrity and build trust in this new approach to clinical trials. This area presents an opportunity for interdisciplinary collaboration between clinical researchers, data scientists and cybersecurity experts.

Regulatory challenges

Regulatory hurdles further complicate the implementation of DCTs.[11,21] Regulatory frameworks vary across regions, introducing additional variance in trial outcomes. For example, the FDA allows eSignature in eConsent, while Germany still requires wet-ink signatures. As such, interpreting DCT results across different regions requires careful consideration of these external factors, such as varying consent procedures, data protection laws and technology acceptance. Apostolaros et al, reported that the CTTI developed recommendations for DCTs, while De Jong et al, emphasized the need for updated regulatory frameworks.[11,26] These findings highlight the evolving nature of DCT regulation and the need for harmonized guidance.

There is a need for harmonized regulatory guidance on DCTs to ensure consistency in the implementation and interpretation of results across different jurisdictions. Developing internationally recognized standards for DCTs could not only facilitate multi-national trials but also potentially accelerate the global adoption of innovative trial designs.

Ethical implications

Ethical concerns also arise in the context of DCTs. Petrini et al, highlighted the complexities of obtaining informed consent in decentralized settings, which could compromise participant understanding.[7] Pascalev further underscored the importance of providing clear, participant-friendly consent process to mitigate this issue.[24] Additionally, the potential for DCTs to exacerbate existing health disparities due to unequal access to technology must be carefully considered and addressed.

The development of clear, participant-friendly consent process for decentralized settings could set new standards for ethical conduct in clinical trials.

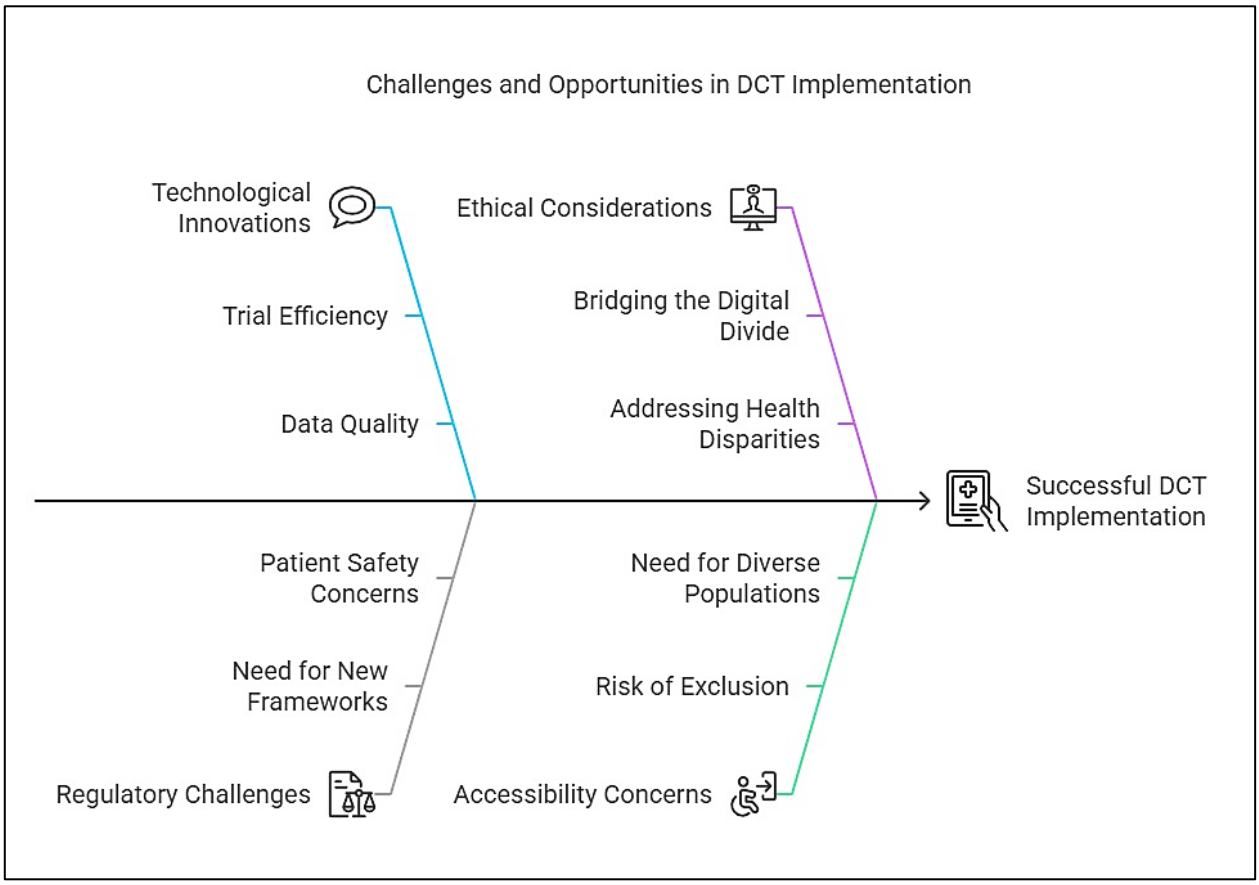

Figure 6: Challenges and opportunities in DCT implementation: A fishbone diagram showing regulatory challenges and technological opportunities, based on 18 studies (2018–2024).

Strengths and limitations of the review

The strength of this review lies in the overall low risk of bias observed in the included studies, as illustrated in Figure 2. This enhances the reliability and credibility of our findings regarding DCTs. However, the exclusion of studies due to poor methodological quality, as seen in 14, poses significant limitations to the generalisability of the review's findings. While ensuring high-quality studies were included, it also limits the diversity of study contexts. The limited timeframe of the studies (2018 to 2024) may exclude older yet still relevant research.

Future reviews might consider a broader inclusion criteria or a longer timeframe to capture a more comprehensive picture of the DCT landscape.

CONCLUSION

DCTs are reshaping the landscape of clinical research, offering innovative solutions to longstanding challenges in patient recruitment, engagement and data collection. This systematic review has revealed both the transformative potential and the persistent hurdles associated with DCTs.

The integration of digital technologies has demonstrated significant improvements in trial efficiency, patient accessibility and data quality. By reducing geographical barriers and minimizing participant burden, DCTs have the potential to create more diverse and representative study populations, addressing a critical gap in traditional clinical research.

Implementation of DCTs, however is not without its challenges. The digital divide poses a risk of inadvertently excluding certain populations, potentially exacerbating existing health disparities. Moreover, regulatory frameworks must evolve to keep pace with these technological advancements, ensuring that innovation does not come at the cost of patient safety or data integrity.

Moving forward, the focus should be on developing standardized best practices for DCT implementation, addressing ethical considerations in remote settings and creating solutions to bridge the digital divide. Further research is needed to fully understand the long-term impacts of DCTs on patient outcomes, drug development timelines and healthcare costs.

In summary, while DCTs offer promising solutions to many challenges in clinical research, their successful implementation requires a balanced approach that leverages technological innovations while addressing ethical, regulatory and accessibility concerns. As this field continues to evolve, ongoing evaluation and refinement of DCT methodologies will be essential to realizing their full potential in advancing medical research and improving patient care.

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REFERENCES

1. Fogel DB. Factors associated with clinical trials that fail and opportunities for improving the likelihood of success: a review. Contemp Clin Tri Commun. 2018;11:156-64.
2. Shea L, Pesa J, Geonnotti. Improving diversity in study participation: Patient perspectives on barriers, racial differences and the role of communities. Health Expect. 2022;25(4):1979-87.
3. Nwolise C, Corrie P, Fitzpatrick R. Burden of cancer trial participation: A qualitative sub-study of the INTERIM feasibility RCT. Chronic Illness. 2023;19(1);81-94.
4. Cameron D, Willoughby C, Messer D. Assessing participation burden in clinical trials: introducing the patient friction coefficient. Clinical Therap. 2020;42(8):150-9.
5. Chaudhari N, Ravi R, Gogtay NJ. Recruitment and retention of the participants in clinical trials: challenges and solutions. Persp Clin Res 2020;11(2); 64.
6. Tew M, Catchpool M, Furler J. Site-specific factors associated with clinical trial recruitment efficiency in general practice settings: a comparative descriptive analysis. Trials. 2023;24(1):1-8.
7. Petrini C, Mannelli C, Riva L. Decentralized clinical trials (DCTs): A few ethical considerations. Front Publ Health. 2022;10:1081150.
8. Betcheva, L., Kim, J. Y., Erhun, F., et al. Applying Systems Thinking to Inform Decentralized Clinical Trial Planning and Deployment. Therap Innova Regul Sci. 2023;57(5):1081-98.
9. Ghadessi M, Di J, Wang C, Toyoizumi K, Shao N, Mei C, et al. Decentralized clinical trials and rare diseases: a drug information association innovative design scientific working group (DIA-IDSWG) perspective. Orphanet J Rare Dis. 2023;18(1):79.
10. Bauer R, Brun S, Owens T, Shortino V. Navigating the challenges of central nervous system disease research. Planning for success in CNS clinical development. 2023.
11. de Jong AJ, Rijssel TI, Zuidgeest MG. Opportunities and challenges for decentralized clinical trials: European regulators' perspective. Clin Pharmacol Therap. 2022;112(2):344-52.
12. Nebie EI, Sawadogo HN, Eeuwijk P. Opportunities and challenges for decentralized clinical trials in sub-Saharan Africa: a qualitative study. BMJ Open. 2023;13(9):75903.
13. Boxall C, Renz S, Eminton Z. Factors that influence women's enrolment and ongoing participation in a partially decentralised randomised controlled dermatology trial: a qualitative interview study with participants in the SAFA (Spironolactone for Adult Female Acne) trial. Trials. 2023;24:661.
14. Goodson N, Wicks P, Morgan J. Opportunities and counterintuitive challenges for decentralized clinical

trials to broaden participant inclusion. NPJ Digital Med. 2022; 5(1); 58.
15. Singh P, Burden AM, Natanegara F. Design and execution of sustainable decentralized clinical trials. Clin Pharmacol Therap. 2023.
16. Cafaro T, LaRiccia PJ, Bandomer B. Remote and semi-automated methods to conduct a decentralized randomized clinical trial. J Clin Translational Sci. 2023;7(1);153.
17. Harmon DM, Noseworthy PA, Yao X. The digitization and decentralization of clinical trials. InMayo Clin Proceed. 2023;98(10):1568-78.
18. Coyle J, Rogers A, Copland R. A secondary qualitative analysis of stakeholder views about participant recruitment, retention and adherence in decentralized clinical trials (DCTs). Trials. 2022;23(1):614.
19. Huh KY, Chung WK, Park J, et al. Feasibility study for a fully decentralized clinical trial in participants with functional constipation symptoms. Clin Transl Sci. 2023;16(11):2177-88.
20. Hoban HG, Yip TA, Chau JC. The motivation and process for developing a consortium-wide time and motion study to estimate resource implications of innovations in the use of genome sequencing to inform patient care. Clin Transl Sci. 2024;17(1):13635.
21. DiMasi JA, Smith Z, Oakley-Girvan I. Assessing the financial value of decentralized clinical trials. Therap Innov Regul Sci. 2023;57(2):209–19.
22. Cummins MR, Burr J, Young L. Decentralized research technology use in multicenter clinical research studies based at US academic research centers. J Clin Transl Sci. 2023;7(1):250.
23. Lau K, Greenwood L, Proctor V. Remote assessments for bone conduction hearing devices during the COVID-19 pandemic. European Arch Oto-Rhino-Laryngol. 2022;279(7):3297-300.
24. Pascalev A. Ethical considerations of decentralized clinical trials. J Clin Transl Sci. 2002;6(1):26–7.
25. Sommer C, Zuccolin D, Arnera V, Schmitz N, Adolfsson P, Colombo N, et al. Building clinical trials around patients: Evaluation and comparison of decentralized and conventional site models in patients with low back pain. Contemp Clin Trial Commun. 2018;11:120-6.
26. Apostolaros M, Babaian D, Corneli A. Legal, regulatory and practical issues to consider when adopting decentralized clinical trials: recommendations from the clinical trials transformation initiative. Ther Innov Regul Sci. 2020;54:779–87.
27. Sehrawat O, Noseworthy PA, Siontis KC, Haddad TC, Halamka JD, Liu H. Data-driven and technology-enabled trial innovations toward decentralization of clinical trials: opportunities and considerations. InMayo Clin Proceed. 2023;98(9):1404-21.

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