Decentralized Trials: Expanding Access, But Facing Digital Hurdles

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Recruitment failures and high attrition rates plague traditional site-based clinical trials, often limiting patient access and diversity. Decentralized clinical trials (DCTs) offer a potential solution, leveraging digital technologies and local healthcare resources to reduce participant burden and broaden reach. But, despite regulatory initiatives, significant hurdles remain for their widespread implementation, particularly in Europe, as detailed in a Delphi study published in J Med Internet Res.1

KEY TAKEAWAYS

- The Pivot: Decentralized clinical trials offer increased accessibility and reduced participant burden compared to traditional models, potentially improving diversity.
- The Data: Widespread adoption remains limited due to operational, regulatory, and technological challenges, including platform fragmentation and digital literacy gaps.1,2,3
- The Action: Clinicians should be aware of DCTs as an option for patients, but recognize the current systemic barriers to their full integration into research.

The COVID-19 pandemic accelerated the emergence of decentralized clinical trials as a model in clinical research. These trials aim to increase accessibility and reduce participant burden by moving some or all trial activities out of traditional research sites and into patients' homes or local healthcare facilities. This shift relies heavily on digital technologies, including telemedicine, wearable devices, and remote monitoring platforms. The promise of DCTs lies in their potential to overcome persistent issues like recruitment failures and high attrition rates that often hinder traditional trials.1,2,3 Traditional clinical trials frequently exclude patients due to geographical distance from study sites, time commitments, and the financial burden of travel. This often leads to study populations that do not reflect the diversity of the real-world patient population, limiting the generalizability of trial results. DCTs, by bringing the trial to the patient, aim to mitigate these barriers, thereby enhancing patient access and fostering greater diversity in trial participants. This is particularly relevant for rare diseases, where patient populations are geographically dispersed and access to specialist centers is limited.1,2,3

The European Regulatory Push and Persistent Hurdles

European regulatory bodies have recognized the potential of DCTs and have initiated programs to facilitate their implementation. The Accelerating Clinical Trials in the European Union program and the European Medicines Regulatory Network recommendation paper, updated in October 2025, represent efforts to streamline the regulatory guidelines for DCTs. These initiatives aim to provide clarity and guidance for sponsors and investigators navigating the

complexities of remote data collection, electronic informed consent, and direct-to-patient drug delivery.1,2

But despite these regulatory tailwinds, the widespread adoption of DCTs remains limited. A Delphi study by Murciano-Gamborino and colleagues, published in 2026, explored the perspectives of multiple stakeholders on the key challenges facing DCTs in Europe.1 The study identified significant operational, regulatory, and technological barriers. Operationally, coordinating remote visits, managing home healthcare providers, and ensuring consistent data quality across diverse settings present considerable challenges. Regulatory hurdles include varying national interpretations of EU guidelines, data privacy concerns (particularly with cross-border data transfer), and the need for clear frameworks for digital informed consent.1

Technological challenges are also substantial. Platform fragmentation, where different digital tools do not seamlessly integrate, creates inefficiencies and complicates data management. Gaps in digital literacy among both patients and healthcare professionals further impede the effective use of these technologies. For instance, older patients or those in rural areas may lack access to reliable internet or the skills to use complex digital platforms, inadvertently creating new access barriers even as others are removed.1

The rapid shift toward remote research models during the COVID-19 pandemic saw 76 percent of pharmaceutical and research organizations adopt decentralized techniques.6 A 2022 review in Frontiers in Public Health highlights that this surge forces Ethics Committees to evaluate new implications for personal data protection and the relationship between patients and healthcare staff.6 This rapid adoption does not establish long-term ethical safety, as the evaluation tools used by these committees remain largely unstandardized. Investigators must now proactively document how they protect data integrity at the source and during transmission to satisfy evolving ethical reviews.

Expanding Access Beyond Geographic Constraints

Haddad and colleagues, writing in JAMA Network Open in 2026, highlighted how a multiregional decentralized clinical trial program could improve access.2 Their work supports the foundational premise of DCTs: to reduce participant burden and increase accessibility. Traditional trials often require patients to travel long distances to specialized academic centers, which can be prohibitive for those with chronic conditions, limited mobility, or financial constraints. DCTs address this by allowing patients to participate from their homes or local clinics, reducing travel time and costs.2

This model is particularly beneficial for patients in underserved areas or those from diverse socioeconomic backgrounds who might otherwise be excluded from research. By broadening the geographical reach, DCTs can enroll a more representative patient population, which is critical for ensuring that new therapies are effective and safe across different demographic groups. A more diverse trial population can also reveal subgroup-specific responses that might be missed in a homogenous cohort.2

The ability to conduct parts of a trial remotely, such as virtual consultations, remote monitoring of vital signs, and electronic patient-reported outcomes, significantly reduces the logistical burden on participants. This flexibility can improve patient retention, as participants are less likely to drop out due to the demands of frequent site visits. The Oxford Handbook of Clinical Medicine provides a comprehensive overview of how such remote monitoring can integrate into broader clinical practice, reflecting the growing trend towards digital health solutions.2

A multi-stakeholder conference involving the United States Food and Drug Administration and the National Institutes of Health concluded that decentralization and digital tools enhance the accessibility of clinical research.7 The 2022 proceedings published in Contemporary Clinical Trials outline that community engagement and improving

representation among clinical research staff are necessary steps to drive lasting change.7 Conference consensus does not equate to a validated operational protocol, and these recommendations lack prospective trial data proving they increase minority enrollment. Trial sponsors should pair remote technologies with local community partnerships rather than relying on digital access alone to diversify their cohorts.

Telehealth's Role, Especially in Rare Diseases

Parisi and colleagues, in their 2026 paper in Ther Adv Rare Dis, specifically examined the challenges and opportunities for telehealth in rare disease diagnosis, treatment, research, and education.3 Rare diseases often present unique challenges for clinical research due to small, geographically dispersed patient populations and a scarcity of expert centers. Telehealth, a core component of DCTs, offers a lifeline for these patients, enabling access to specialized care and research opportunities that would otherwise be out of reach.3

For rare disease trials, DCTs can facilitate recruitment by eliminating the need for patients to travel to a limited number of highly specialized sites. This is especially important when a disease is ultra-rare, and the patient pool is spread across an entire continent. Telehealth allows for remote consultations with specialists, remote data collection, and even home-based administration of certain therapies, all of which reduce the logistical and financial strain on patients and their families.3

The authors, through key opinion leader interviews by the IRDiRC telehealth task force, identified that while telehealth offers significant opportunities, it also faces similar challenges to broader DCT implementation. These include the need for robust digital infrastructure, consistent regulatory frameworks across different regions, and adequate training for both patients and healthcare providers in using telehealth platforms. Ensuring data security and privacy, particularly for sensitive rare disease patient data, remains a paramount concern.3

European Reference Networks now utilize the Clinical Patient Management System to facilitate cross-border expert collaboration for complex genetic cases.8 A 2026 paper in the Journal of Community Genetics notes that integrating real-world evidence from wearables with advanced analytics provides objective data to support regulatory decisions.8 These digital platforms do not overcome the inability to perform comprehensive physical examinations remotely, leaving a gap in trials requiring precise phenotypic assessments. Clinicians designing rare disease trials should adopt a hybrid model of care that strategically combines telemedicine with essential in-person interactions.

Operational Complexities and Data Integrity

Implementing DCTs introduces a new layer of operational complexity that traditional trials do not encounter. Managing a network of local healthcare providers, ensuring they adhere to study protocols, and maintaining consistent training across diverse sites requires robust oversight. The logistics of direct-to-patient drug delivery, including cold chain management and accountability, add further challenges. Sponsors must develop sophisticated supply chain management systems to ensure investigational products reach patients safely and on schedule.1

Data integrity is another critical area. While digital tools can streamline data collection, they also introduce new vulnerabilities. Ensuring the accuracy, completeness, and reliability of data collected remotely from various sources (wearables, patient apps, local labs) requires advanced data management systems and rigorous validation processes. The fragmentation of digital platforms, where different vendors offer disparate solutions, complicates this further, often requiring custom integrations that are costly and time-consuming to develop and maintain.1

The regulatory environment, while evolving, still presents a patchwork of requirements across European countries.

Harmonization of guidelines for electronic informed consent, remote monitoring, and data privacy (e.g., GDPR compliance) is essential for seamless cross-border DCTs. Without clear, consistent guidance, sponsors face increased administrative burden and potential delays in trial initiation.1

Applying a decentralized model to phase 1 clinical trials could improve patient accrual and strengthen evidence for rare tumors in early drug development.5 A 2024 framework proposal in the Journal of Immunotherapy and Precision Oncology notes that evidence of feasibility currently comes mainly from phase 2 and 3 clinical trials.5 Observational data from late-stage trials do not establish the safety of remote administration for unproven investigational products in phase 1 studies. Sponsors moving early-phase research into patients' homes must build rigorous safety monitoring protocols that exceed the standards used in conventional late-phase decentralized trials.

Digital Literacy and Patient Engagement

A significant barrier to widespread DCT adoption is the variability in digital literacy among the patient population and healthcare professionals. Not all patients have access to smartphones, reliable internet, or the technical proficiency to navigate complex health apps. This digital divide risks exacerbating health inequalities, potentially excluding vulnerable populations who could benefit most from increased trial access. Training and support for patients on how to use digital tools are vital for successful trial participation, but often overlooked.1

For healthcare professionals, adapting to new digital workflows and integrating remote patient management into their existing practices requires substantial training and a shift in mindset. Many clinicians are accustomed to in-person interactions and may be hesitant to fully embrace virtual care models without adequate support and clear guidelines. The successful implementation of DCTs hinges on effective patient engagement strategies that go beyond simply providing technology, focusing instead on user-friendly interfaces, clear communication, and readily available technical support.1

Rapid advancements in digital technologies facilitate virtual interactions by making it easier to collect and store electronic data.4 A 2024 review in Nature Medicine warns that these innovations are associated with challenges that may create or worsen existing health inequalities.4 Identifying barriers does not automatically generate solutions, and the literature lacks controlled trials comparing different digital literacy interventions in underserved groups. Research teams must actively screen participants for technological proficiency during enrollment and provide dedicated devices to prevent the exclusion of vulnerable populations.

The same review provides recommendations to promote equity and inclusion in decentralized clinical trials.4 By describing the key barriers individuals from underserved groups face, the authors aim to enhance clinical trial participation in an equitable manner.4 Broad recommendations do not guarantee generalizability across all therapeutic areas or geographic regions. Investigators should tailor their patient engagement strategies to the specific demographic profile of their target disease rather than applying a universal digital framework.

The Path Forward: Collaboration and Standardization

The path to widespread DCT adoption requires a concerted effort from all stakeholders: regulators, pharmaceutical companies, technology providers, healthcare systems, and patient advocacy groups. Standardization of digital platforms and interoperability between different systems would significantly reduce the technological fragmentation that currently hinders DCTs. Developing common data standards and security protocols is also essential to build trust and ensure compliance.1

Regulators must continue to refine and harmonize guidelines across Europe, providing clear, consistent frameworks that support innovation while safeguarding patient rights and data privacy. Pilot programs and real-world evidence from ongoing DCTs will be vital for informing these evolving guidelines. Investing in digital literacy programs for both patients and healthcare providers can help bridge the digital divide, ensuring that the benefits of DCTs are accessible to all.1

The consensus points towards a hybrid model of research that maximizes patient knowledge capital and accelerates therapeutic development.8 Future directions outlined in the Journal of Community Genetics include rigorously evaluating the clinical outcomes of telemedicine and fostering coordinated collective intelligence networks.8 Theoretical frameworks for international policy harmonization do not resolve the immediate legal conflicts sponsors face when transferring patient data across borders today. Trial designers must navigate current fragmented regulations by building redundant compliance measures into their digital platforms while waiting for global standards to mature.

"The widespread adoption of DCTs remains limited due to significant operational, regulatory, and technological challenges, including platform fragmentation and gaps in digital literacy."Murciano-Gamborino C, J Med Internet Res 2026The open-label design of some early DCTs is an obvious caveat, as blinding can be more challenging in a remote setting. The trials were not powered to detect differences in specific underserved subgroups, and that gap matters for understanding true equity of access. Whether the benefits of DCTs, particularly in terms of diversity and retention, extend uniformly across all disease areas and patient populations remains unclear, requiring further dedicated research. The next phase of DCT development must focus on robust, randomized studies that directly compare decentralized and traditional models on key outcomes beyond just recruitment, including data quality, patient safety, and clinical efficacy.1,2,3

CLINICAL IMPLICATIONS

Decentralized clinical trials represent a necessary evolution in medical research, particularly for European GPs and specialists who often see patients struggling with access to specialized care and clinical trials. The promise of increased patient diversity and reduced burden is substantial, offering a pathway to more generalizable and equitable research outcomes. But, the current reality is that these trials are not yet a seamless solution.

Clinicians referring patients to trials should be aware of the operational and technological hurdles that still exist. While the idea of a trial coming to the patient is appealing, issues like platform fragmentation and varying digital literacy mean that the experience can be inconsistent. It is not enough to simply offer a remote option; the infrastructure must support it reliably, and patients need clear, accessible technical assistance.

For industry, the ongoing regulatory initiatives in Europe are a positive step, but the slow pace of harmonization across member states creates a complex environment. Until there is greater clarity and consistency in guidelines for remote consent, data transfer, and direct-to-patient logistics, the full potential of DCTs will remain untapped. This fragmented regulatory market adds cost and complexity, which ultimately slows down the development of new therapies.

The ultimate goal of DCTs is to bring research closer to the patient, making participation feasible for a wider demographic. But this requires more than just technology; it demands a fundamental rethinking of how trials are designed, regulated, and executed. Without addressing the underlying operational and digital literacy gaps, DCTs risk creating new forms of exclusion, rather than truly democratizing access to clinical research.

> The Oxford Handbook of General Practice highlights the importance of patient-centered care, a principle that must extend fully into clinical trial design.

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