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# Decentralized Clinical Trials and Digital Submissions: How Regulatory Affairs is Reinventing Itself in the Post-pandemic Era

**Makkos Brundin***

*Department of Regulatory Affairs, Novartis Pharma AG, 4001 Basel, Switzerland*

## Introduction

The COVID-19 pandemic served as a catalyst for transformative change in the clinical research landscape, compelling the adoption of Decentralized Clinical Trials (DCTs) and digital submission processes. These innovations have not only addressed immediate challenges posed by the pandemic but have also paved the way for a more patient-centric and efficient approach to clinical research. Regulatory bodies worldwide have responded by evolving their frameworks to accommodate these changes, ensuring that the integrity and safety of clinical trials are maintained while embracing technological advancements. Decentralized Clinical Trials (DCTs) are studies where some or all trial-related activities occur at locations other than traditional clinical trial sites. This model leverages digital health technologies, telemedicine and mobile health applications to conduct trials remotely, allowing patients to participate from their homes or local healthcare facilities [1].

Virtual visits between patients and healthcare providers to monitor health status and collect data. Use of wearable devices and mobile applications to track patient health metrics in real-time. Arrangements with local labs for sample collection and analysis, reducing the need for patient travel. Utilization of electronic data capture systems to collect and manage trial data efficiently. Patients can participate from the comfort of their homes, eliminating geographical barriers and reducing the need for frequent travel to clinical sites. The flexibility and convenience of remote participation can lead to higher patient engagement and retention rates. DCTs can reduce operational costs associated with physical trial sites and streamline data collection processes, leading to faster trial timelines. By removing traditional barriers, DCTs can include a more diverse group of participants, enhancing the generalizability of study results [2].

## Description

In the United States, the Food and Drug Administration (FDA) has taken proactive steps to support the use of DCTs. In May 2023, the FDA released draft guidance providing recommendations for sponsors and investigators on implementing DCTs. Recommendations on structuring trials to incorporate decentralized elements effectively. Guidelines for conducting virtual visits and monitoring patient safety remotely. Best practices for integrating digital tools into trial protocols. Approaches to obtaining and documenting informed consent remotely. Strategies for ensuring participant safety in a decentralized setting . The European Medicines Agency (EMA) has also recognized the potential of DCTs. In 2022, the EMA issued a recommendation paper emphasizing patient safety and data integrity in decentralized trials. The European Union's Clinical Trials Regulation effective from early 2022, includes provisions for remote monitoring and electronic medical records, facilitating the implementation of DCTs across member states. Countries like Canada and Australia are exploring regulatory frameworks to support DCTs. Health Canada has initiated a clinical trial regulatory modernization program, while Australia is actively integrating digital health technologies into clinical research practices [3].

The shift towards digital submissions has been instrumental in modernizing regulatory affairs. Digital formats expedite the review process, reducing the time required for regulatory approvals. Electronic submissions minimize errors associated with manual data entry and ensure consistency in documentation. Digital systems provide clear audit trails, enhancing accountability and traceability. Stakeholders can access submission materials remotely, facilitating collaboration and communication. Regulatory bodies have developed specific guidelines to facilitate digital submissions. For instance, the FDA has updated its guidance on electronic systems, electronic records and electronic signatures in clinical investigations, ensuring that digital submissions meet regulatory standards. The reliance on digital tools necessitates stringent measures to protect patient data. Compliance with regulations like the General Data Protection Regulation (GDPR) in Europe and the Health Insurance Portability and Accountability Act (HIPAA) in the U.S. is essential. Obtaining informed consent remotely requires careful consideration to ensure that participants fully understand the trial procedures and their rights. Ensuring the accuracy and reliability of data collected through digital means is crucial for maintaining the scientific validity of trials. Different countries have varying regulations regarding DCTs, necessitating a nuanced approach to ensure compliance across jurisdictions [4].

To address these challenges, sponsors and investigators must implement robust compliance strategies. Utilizing encrypted communication channels and secure data storage solutions. Ensuring that all team members are knowledgeable about regulatory requirements and best practices. Maintaining open communication with regulatory bodies to stay informed about evolving guidelines. The post-pandemic era has ushered in a new paradigm for clinical research. The integration of DCTs and digital submissions is expected to continue evolving, with several trends emerging. Combining traditional site-based visits with decentralized elements to offer flexibility and maintain data integrity. Leveraging AI and ML to analyze large datasets, predict patient outcomes and personalize treatment plans. Focusing on patient preferences and experiences to design trials that are more inclusive and accessible. Facilitating international trials through standardized digital platforms and harmonized regulatory frameworks. Regulatory bodies will play a pivotal role in shaping the future of clinical trials by developing adaptive and forward-thinking policies that support innovation while ensuring patient safety and data integrity [5].

## Conclusion

Decentralized Clinical Trials and digital submissions represent a significant shift in the clinical research landscape. These innovations have not only enhanced the efficiency and accessibility of clinical trials but have also prompted regulatory bodies to modernize their frameworks to accommodate these changes. As the industry continues to evolve, ongoing collaboration between sponsors, investigators and regulatory authorities will be essential to navigate the complexities of this new era in clinical research.

***Address for Correspondence:** Makkos Brundin, Department of Regulatory Affairs, Novartis Pharma AG, 4001 Basel, Switzerland; E-mail: brundinakkam@und.ch*



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## Conflict of Interest

There are no conflicts of interest by author.

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