

# Viewpoint: Decentralized Clinical Trials Have Arrived and Staying for Good



Mary Suzette R. Cody, MDM\*

## ABSTRACT

The Covid-19 pandemic challenged every healthcare system, and the disruption of clinical trials was not the least of it. Many clinical trials halted or did not activate as sponsors and investigators grappled with the risk of infection if patients involved in clinical trials visited trial sites. The clinical studies that managed to continue and complete were those that immediately adopted decentralized clinical trials (DCT) technologies such as eSource. Patients were engaged from the comfort and convenience of their homes during the clinical trials with the use of DCT technologies. The flexibility in recruitment, engagement, and monitoring of clinical trial participants are among the reasons why DCTs are here to stay.

## INTRODUCTION

The Covid-19 pandemic challenged every healthcare system, and the continuity of clinical trials was not the least of it. Many clinical trials were halted or did not activate as sponsors and investigators grapple with the risk of infection if patients involved in clinical trials visit trial sites.

A retrospective cohort study examined 62,252 trial activations and found that during the initial Covid-19 outbreak (February 2020 through May 2020), only 57% of the US trials were initiated compared to estimates if the pandemic did not occur.[1] Any

kind of delay in clinical research impacts new drug discoveries and innovative therapies for patients.[2]

Some studies, however, were able to continue with the application of decentralized clinical trials (DCT) technologies. eSource is one among those technologies.

## ESOURCE

In 2013, the U.S. Food and Drug Administration (USFDA) issued a guidance “to promote streamline and capture source data in electronic form, and it is intended to assist in ensuring the reliability, quality, integrity, and traceability of data from electronic source to electronic regulatory submission.”[3] Instead of entering data on paper and transcribing them into an electronic database, there will be direct electronic source data capture or eSource.

The use of eSource for clinical research became the basis for the transition from traditional paper-based data intake for eventual electronic data capture (EDC) to direct data capture using electronic-based health records (EHR), medical records (EMR), smart devices, including wearables, survey and monitoring apps and testing records, among others.[4,5]

Through the public health emergency notification during the pandemic, the USFDA provided guidance on how clinical studies could be more flexible to continue and complete.[6] Study teams were allowed to deliver experimental medicines to participants’ homes. For their safety, the participants were able to consent to studies through online platforms and were monitored remotely. For basic procedures and assessments, participants could visit a local doctor instead of travelling some distance to the study sites.

✉ Mary Suzette R. Cody, MDM  
suzcody@icloud.com

\* Master in Development Management  
Medical Writer, American Medical Writers Association

## DCT

When the pandemic hit, some sponsors, clinical research organizations and investigators were able to incorporate existing DCT solutions to minimize the disruption to clinical studies. Technology providers of DCT were agile enough to customize studies according to changing needs of clinical trials. The March 2022 White Paper issued by the Association of Clinical Research Professionals, notes that the “potential benefits of DCT include a reduced need for sponsor and study site resources, and a better, more convenient study subject experience with fewer, shorter clinic visits and less frequent face-to-face contact.”[7]

The patients’ safety and convenience became more pronounced during the pandemic. It was inevitable that as a result, telemedicine rose in popularity and use. In the US alone, the number of people using telehealth increased to 46% in 2020 from 11% in 2019, according to a 2020 report by McKinsey and Co.[8]

From consumers of telemedicine to participants in clinical trials, as a result of the pandemic experience patients became more engaged and empowered in making their contribution to public health. The convenience and flexibility of the virtual or remote consent process, use of smart wearables, medicine

delivery, online feedback system and monitoring are among the essential features of DCT to reach and engage participants and encourage adherence to protocol.

## CONCLUSION: THE FUTURE OF DCT

DCT became a significant response during the pandemic to enable the continuity of clinical trials. In the current period, more studies are using DCT technologies because the future of clinical trials includes “meeting patients where they are”.[6] Patients participating in clinical trials that are decentralized are encouraged to stay engaged and compliant with protocol, particularly with their safety and convenience fully considered through the use of DCT solutions. The flexibility in remote recruitment and engagement, and monitoring of clinical trial participants are among the reasons why DCT are here to stay.

While DCT are here to stay, some concerns related to “potential missed opportunities to detect safety signals, increased data errors, and greater reliance on study subject compliance” still need to be continually addressed.[9] It is safe to assume that there will be more assessments related to DCT performance in the years to come.

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