

Case Study: Use of Decentralized Clinical Technologies in Lower Urinary Tract Symptoms



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“The biggest risk is not taking any risk”
Facebook’s Mark Zuckerberg, Stanford University
in 2011.

ABSTRACT

A clinical study with 49 participants was started and completed at the height of the Covid-19 pandemic with the use of decentralized clinical trial (DCT) methodologies. All participants and the study team remained safe and were able to conduct the study efficiently. Patients were able to provide consent electronically, received experimental supplements and were given the option to provide feedback through the system’s telemedicine feature.

INTRODUCTION

As the pandemic surged in 2021, a clinical trial to evaluate the impact of Crinum latifolium extract, oral Crila[®] capsules on lower urinary tract symptoms (LUTS) was about to be activated. With not enough information to assess the safety risk of having patients go to the clinical investigation sites, the study could not start. The safety risk was high. The economic cost of delay or discontinuance of the study was equally high. The sponsor and study team had to weigh the risks competently.

With a guidance series from the USFDA, flexible conduct of clinical trials during a public health emergency became possible to fully implement remote consent, virtual monitoring, and medicine delivery to the participants’ homes.[1] The application of innovative and agile clinical trial technologies known as decentralized clinical trial (DCT) methodologies provided the much-needed solutions to the disruption wrought by the pandemic to clinical studies in general. The LUTS study proceeded, utilizing remote tools which not only ensured participant compliance but also managed the risks effectively.

DCT IN THE CLINICAL STUDY CASE

The clinical study on LUTS and the use of Crila[®] capsules commenced in two sites in Mexico as soon as technologies for virtual clinical trials were in place. DCTs like eSource, remote data monitoring and medicine delivery tracking, with a built-in electronic data collection were immediately customized for the needs of the LUTS study. The study staff were trained via Zoom.

All 49 participants were able to participate in the study by using electronic consent (eConsent) with a smart device which meant that there was no traditional paper documentation in the consent process. Except for one visit for basic assessment at a clinical site near their homes, the participants were monitored remotely. An online feedback system through surveys encouraged participants to be more compliant with the protocol requirements.

With DCT methodologies, the study team also remained safe from possible Covid exposure at the clinical sites. Data from the trial were seamlessly transferred from the electronic data collection system

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to data analysis platforms. After four months, the study was successfully completed and closed in the last quarter of 2021.

The LUTS clinical study was one of many examples of the successful application of DCT during a pandemic. Vaccine studies which were fast-tracked through phase III in order to get the filing for emergency use access (EUA) adopted DCT methodologies and tools. [2] About 4,576 decentralized trials in the US were launched in June 2021. [3] From Deloitte's report in 2022, 92% of patients expressed that clinical trials use innovative technology. [4] The USFDA supports the use of decentralized methods for more efficient trial timelines and to increase patient retention.

CONCLUSION

The clinical study conducted in two sites was completed on time. This would not have been possible without DCT solutions that assured safety and convenience for patients. Patients' experiences with remote participation in clinical trials using decentralized solutions are very much on par with their increasing use of telehealth services for their healthcare. When patients feel safe and their convenience is factored into the conduct of a clinical study, they are more responsive and compliant with the protocol to complete the study.

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