Decentralised clinical trials: a game changer for improved access to clinical trials

The US Food and Drug Administration has issued guidance on decentralised clinical trials, which are a game changer for the conduct of clinical trials.[1] This guidance encourages the use of telehealth to conduct clinical trials outside traditional trial centres and discusses ongoing issues, such as the coordination of care between multiple providers.

The Australian Teletrial Model is a robust version of decentralised clinical trials with some advantages, addressing issues raised in the guidance.[2] The hallmark of the Australian Teletrial Model is the formation of active partnerships between the main trial site and remote local health-care providers and uses a supervision plan to document roles and responsibilities.[3] The supervision plan can be considered a site delegation log across a network. A risk-based approach is used to designate trial-related procedures to be conducted at remote sites, according to the complexity of the intervention and the capability of the site. Principal investigators retain responsibility for the conduct of the study. Principal investigators and sponsors can use telehealth for training, supervision of meetings, and remote monitoring of sites, which are activities that became widespread during the COVID-19 lockdown period. Telehealth elements should be considered during the design of the study with the involvement of participants to test the acceptability of procedures.

Rural populations and other socially disadvantaged groups are well documented to have reduced access to clinical trials. Enrolment in cancer clinical trials might improve survival, perhaps not only by accessing new drug interventions, but because of more direct access to clinical trial staff who are able to identify and address symptoms and enable a longer duration of care. This could be especially important for populations with reduced access to health care in general.

Advantages of decentralised clinical trials and the Australian Teletrial Model include improved health equity for rural and disadvantaged populations allowing more to be cared for in their own communities; improved diversity of trial participants enabling more real-world trial populations; better recruitment, retention, and satisfaction of trial participants;[4] better return on investment for sponsors by bringing drugs to the market quicker;[5] reduced costs for the health-care system; upskilling of rural workforces; and expanding the capabilities of rural sites.

We hope that the Food and Drug Administration guidance results in the rapid uptake of decentralised clinical trials. Service-level improvements might not be as attractive as a new targeted therapy but could be more impactful at improving outcomes for disadvantaged patients. It is time for sponsors, investigators, and health administrators to embrace decentralised clinical trials just as health services have embraced electronic medical records and other systems innovations.

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1 US Department of Health and Human Services, Food and Drug Administration. Conducting clinical trails with decentralized elements. Guidance for industry, investigators, and other interested parties. 2024. https://www.fda.gov/media/167696/download (accessed Oct 21, 2024).

2 Sabesan S, Malica M, Gebbie C, Scott C, Thomas D, Zalcberg J. Implementation of the Australasian Teletrial Model: translating idea into action using implementation science frameworks. *J Telemed Telecare* 2023; **29:** 641–47.

3 Underhill C, Freeman J, Dixon J, et al. Decentralized clinical trials as a new paradigm of trial delivery to improve equity of access. *JAMA Oncol* 2024; **10:** 526–30.

4 Alexander M, Harris S, Underhill C, et al. Risk-directed ambulatory thromboprophylaxis in lung and gastrointestinal cancers: the TARGET-TP randomized clinical trial. *JAMA Oncol* 2023; **9:** 1536–45.

5 DiMasi JA, Smith Z, Oakley-Girvan I, et al. Assessing the financial value of decentralized clinical trials. *Ther Innov Regul Sci* 2023; **57:** 209–19.