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Themed Issue

Decentralized research: realizing the promise of virtual clinical trials

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Decentralized clinical research is characterized by how participants are engaged. In a decentralized study, research activities are taken to the participant rather than requiring the participant to attend the researcher's clinic. The promise of decentralized research includes removing geographic barriers to research participation and extending reach from academical medical centers into community settings. The expectation is to increase the generalizability of research, leveraging technology and home visits to allow for remote study procedures and data capture that bring the research to the participant. Despite the promises, little is yet known about the operational performance of decentralized studies.

Critical questions include whether access to decentralized is equitable, whether the consent process enhances informed decision making, and how different data collection methods support data quality and timeliness. It remains uncertain which interventions are safe to evaluate in a decentralized study and, for higher risk interventions, what safety monitoring is required or can be accomplished in a remote environment. With the opportunity for collecting a plethora of non-clinical data, including environmental and social determinants of health (SDOH) data,

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wearables, patient reported outcomes, and even shopping or lifestyle habits, decentralized research is supporting the emergence of novel methods, new outcomes, and statistical innovations to improve the efficiency of learning from data.

This themed issue of JCTS will cover the current state of knowledge around decentralized trials, disseminate the innovations and approaches that are being successfully deployed, and will highlight the regulatory, ethical, and methods developments needed to accelerate the migration of research from the hallowed halls of healthcare into the homes of patients and their families. Through this open call, we are soliciting manuscripts that contribute to understanding and improving the decentralized research process, including but not limited to:

- Strategies for recruitment and retention into decentralized trials
- Strategies to optimize diversity and reach
- Evaluation of data quality and validity in decentralized trials
- Capturing safety signals remotely
- Novel data science approaches and opportunities for efficiency with non-traditional follow-up schema
- Regulatory and ethical challenges and solutions to conducting human subjects research at a distance from the participant
- Institutional responsibilities and guidance for conducting research that crosses state borders

Submissions should be made online via the Journal's ScholarOne submission site. Authors are asked to select **Decentralized research: realizing the promise of virtual clinical trials** Themed Issue submission question when submitting to this issue. Accepted articles will be published online in FirstView ahead of being compiled into the themed issue. Only articles submitted prior to March 30, 2023, will be considered for inclusion in this themed issued.

Manuscripts may be submitted for peer review in any of the Journal's article types listed here. For a full description of each manuscript category, as well as, information on the submission of manuscripts, journal policy and journal style, please visit the JCTS Instructions for Contributors on Cambridge Core.

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Questions regarding this themed issue should be directed to the Guest Co-Editors listed above via the JCTS Editorial Office (jcts@cambridge.org).