Themed Issue

Innovations for Enhancing the Informativeness and Quality of Clinical Trials

Journal of Clinical and Translational Science



Laura P. James, MD

Director, University of Arkansas for Medical Sciences (UAMS) Translational Research Institute

Associate Vice Chancellor for Clinical and Translational Research, UAMS

Professor of Pediatrics, Arkansas Children's Hospital and UAMS

Robert Kimberly, MD

Howard L. Holley Professor of Medicine Director, Center for Clinical and Translational Science Senior Associate Dean for Clinical and Translational Research, UAB School of Medicine Associate Vice President for Medicine and Biomedical Research

Christopher John Lindsell, PhD

Professor of Biostatistics and Biomedical Informatics Director, Vanderbilt Institute for Clinical and Translational Research (VICTR) Methods Program

Co-director, Vanderbilt Health Data Science (HEADS) Center Associate Director, Center for Clinical Quality, and Improvement Research

Jareen K. Meinzen-Derr, PhD, MPH, FACE

Professor of Pediatrics, University of Cincinnati College of Medicine

Associate Director, Division of Biostatistics and Epidemiology, Cincinnati Children's Hospital Medical Center

Co-Director, Center for Clinical and Translational Science and Training

University of Cincinnati College of Medicine

Ruth O'Hara, PhD

Senior Associate Dean for Research, Stanford University School of Medicine,

Director, Stanford Clinical and Translational Science Award (CTSA)

Lowell W. and Josephine Q. Berry Professor, Department of Psychiatry and Behavioral Sciences, Stanford University School of Medicine

Director, Sierra-Pacific MIRECC Translational Core

The informativeness of clinical trials has been called into question in recent years. Clinical trials that fail to provide informative data drain valuable resources in academic health centers and place unnecessary burdens on clinical research staff, administrative and regulatory bodies, and human subjects research infrastructure. More importantly, the ethicality of enrolling participants into trials that are uninformative is questionable.

Uninformative clinical trials fail to advance translational science, they fail to inform clinical decision making and health care policy, and they do a disservice to research participants and the communities they represent, thus raising questions about academic oversight.

In this context, the urgency and magnitude of the COVID-19 pandemic promulgated multiple clinical trial innovations from adaptive platform trials to decentralized and virtual trials. New approaches to sharing data among trials, and for overseeing multiple trials of similar agents have been explored. Many of the innovative trials reflect a greater utilization of realworld approaches and have leveraged adaptive designs. Newer approaches reflect a greater utilization of realworld approaches, and they leverage adaptive designs and alternative statistical paradigms. The lessons learned from the launch and implementation of these clinical trials, particularly regarding their quality and informativeness, have yet to be disseminated.

Clinical and translational scientists have a responsibility to educate and train students and junior faculty on





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best practices to optimize clinical trial design so that data are of value. This value may be in finetuning future approaches for larger trials in development, or providing information that can guide clinical, regulatory or policy decision making. The informativeness of clinical trials must be contextualized in the broad application of their findings to a diverse community, as well as the potential for translating clinical trial findings into practice.

This themed issue of JCTS is expected to address broad issues related to improving the informativeness and quality of clinical trials. Through this open call, we are soliciting manuscripts that contribute to understanding and improving the informativeness of trials, including but not limited to:

- Strategies to enhance the quality of clinical trials
- Strategies to optimize diversity in clinical trial design
- Contributions of implementation science toward optimizing clinical trial design
- Lessons learned from adaptive and real-world clinical trial designs during COVID-19
- Enhancing clinical trial design through cohort exploration in electronic health care systems
- Benefits of clinical trial management systems
- Educational approaches for clinical trial design
- Optimizing clinical trials for the digital age
- Institutional responsibilities and best practices for conducting clinical trials

Submissions should be made online via the Journal's ScholarOne submission site no later than January 31, 2023. Authors are asked to select Innovations for Enhancing the Informativeness and Quality of Clinical Trials for the 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.

Manuscripts may be submitted for peer review in any of the Journal's article types listed <u>here</u>. 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 <u>JCTS</u> <u>Instructions for Contributors</u> on Cambridge Core.

JCTS is a fully Gold Open Access journal. Information on the Journal's Open Access policies, including the current Article Processing Charge, can be found <u>here</u>. For additional information regarding the mission to the journal, see <u>http://www.actscience.org/page/</u> journal-of-clinical-and-translational-science_

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

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