Clinical Coordinating Center
Massachusetts General Hospital
55 Fruit Street, 5LON207
Boston, MA 02114

Data Coordinating Center
Massachusetts General Hospital
165 Cambridge Street Suite 400
Boston, MA 02114

The importance of methods for site performance evaluation in REPRIEVE, a longitudinal, global, multicenter trial

Evelynne S. Fulda, Steven K. Grinspoon, Kathleen V. Fitch, and colleagues

Published in Contemporary Clinical Trials, 2022

Background

REPRIEVE enrolled more than 7500 participants at over 100 clinical research sites (CRSs) in 12 countries. Each CRS contributes to the overall success of REPRIEVE. As such, it is important that each CRS meets prespecified trial performance goals which include retention of participants and data entry. Meeting trial performance goals allows for efficient trial completion and operational success. The ultimate goal of completing a randomized controlled trial is to inform clinical care – working to meet trial performance standards helps to ensure that this goal will be met.

Methods

Guidance on evaluating the performance of CRSs in large randomized clinical trials is limited. In this paper, we described the methods used in REPRIEVE to evaluate CRS performance. We looked at three specific performance metrics:

- Participant retention (maintaining ongoing participation in the trial)
- Data management (how data are collected and entered into the electronic data capture platform)
- Specimen management (how blood samples are collected, entered into the laboratory data management system, and sent to the central repository)

REPRIEVE has multiple methods for supporting and evaluating CRS performance:

- Creation of a site performance plan to set out standards for evaluation and assessment of CRS performance
- Development of CRS performance summary reports to monitor performance in real-time
- Multiple channels of communication with CRSs designed to share updates and provide trial-wide and site-specific feedback

In Summary: Although REPRIEVE is ongoing, we looked at CRS performance from April 2019 (when enrollment was nearing conclusion) to April 2022 to describe site performance in the trial so far. Overall, CRS performance has been consistent over time and in line with prespecified trial performance goals, and targeted messaging relating to certain performance metrics was effective. Our methods for evaluating trial performance have allowed for real-time feedback and support, and, when needed, site-specific assistance. This has been especially helpful during the COVID-19 pandemic as it allowed for a change in certain study procedures to adapt to a changing world. This paper is designed to serve as a guidepost for future clinical trials to ensure successful trial completion.