

Optimizing Clinical Trials: A Deep Dive Where Methodology meets Management

Abstract:

Through 25 years of collaboration and creativity, we have combined our clinical and biostatistical resources to successfully produce methodology and interactive management tools to address the ever-increasing needs of designing and conducting multisite, international clinical trials. The team-based approach of the Data Coordination Unit (DCU) at the Medical University of South Carolina integrates the expertise of our team of PhD Biostatisticians and Clinical Trial Management Specialists with the expertise of our clinical and basic science colleagues throughout the world. Our interactive approach to the design and implementation of addressing clinical research questions demonstrates how the role of the collaborative biostatistician is critical to the journey of discovery. This collaboration also allows the DCU to continually evolve the overarching functionality of our internally developed clinical trials management system, WebDCU™, to address the clinical design and implementation needs of over 100 clinical trials. We consider optimization from three perspectives: from the clinician's perspective, the trial design perspective, and the trial implementation perspective. This presentation will explore each of these perspectives by focusing on integration, automation, and generalization within these three domains. Examples from current and future clinical trials will be presented demonstrating how optimization and biostatistical contributions have enhanced methodology and management.