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Educating for Reproducibility: Pathways to Research Integrity

Modeling Good Clinical Practice Principles from Clinical Trials to Improve Rigor, Reproducibility, and Transparency in Single Laboratory Studies: An Example from ACTIVE

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ABSTRACT

Objective: Applying Advanced Cognitive Training for Independent and Vital Elderly (ACTIVE) as an example clinical trial, we present the ways in which good clinical practice principles in clinical trials can be implemented in the smaller laboratory/study environment to promote rigor, reproducibility, and transparency.

Background: Rigor, reproducibility, and transparency are key for producing findings with greater certainty. Clinical trials are governed by principles of good clinical practice, which can strengthen the achievement of rigor, reproducibility, and transparency in scientific research. Clinical trials are greatly supervised, often by a clinical trial coordinating center, data safety and monitoring board, and a funding agency, with policies that are a manifestation of good clinical practice and support rigor, reproducibility, and transparency.

Example and Implementation: ACTIVE was an NIH funded multi-site Phase 3 clinical trial, aimed at investigating the immediate and long-term impacts of cognitive training on older adults' independence and everyday functioning. ACTIVE utilized many protocols that can be applied to single laboratory designs, including: a manualized protocol with accompanying scientific rationale, predefined analysis plans, standardization of procedures across field sites, assurance of competence of study staff in study procedures, the transparent coding/entry/transmittal of data, regular quality assurance, and open publication of data.

Conclusion: Despite substantial resource discrepancies between the two, single laboratory studies can model the good clinical practice principles utilized in large clinical trials to provide an excellent foundation for rigor, reproducibility, and transparency.