

**PROJECT ImpACT: IDENTIFICATION AND SELECTION OF THE MOST IMPORTANT RCTs EVER DONE**

**Steven N. Goodman, Harry M. Marks and Karen A. Robinson**

*The Johns Hopkins University Schools of Medicine and Public Health  
Baltimore, Maryland, USA*

**Introduction:** In spite of the acknowledged centrality of the RCT to the healthcare knowledge base, there is no comprehensive source that documents the contributions of landmark trials across all domains of healthcare. Project ImpACT, an NIH funded initiative, aims to fill that gap by identifying and comprehensively describing the most important RCTs conducted since 1948, the year of the first large-scale RCT in medicine.

**Methods:** There are two main methodologic issues in the project. The first is the development of criteria for types of impact, and what will constitute evidence for each type. The second issue is the identification of RCTs that meet these criteria, and how to apply them. The formulation of the criteria and selection of trials from a nominated pool is being done by an international advisory board of experts in RCTs and evidence-based medicine. The nominations of potential ImpACT Trials are being sought from a network of clinical and methodological experts and through an online, open nomination process, which can be viewed on the Project ImpACT website ([www.projectimpact.info](http://www.projectimpact.info)). This will ultimately be published in a compendium that will try to go beyond typical trial reports, providing the story “behind” each trial, the political and scientific context in which design choices were made, and the responses to the trial.

**Results:** A preliminary list of domains of impact has been developed, and includes impact on the practice of medicine or public health; on the methods of designing, conducting or analyzing trials; on the course of subsequent research; on the understanding of pathophysiology and biology; on regulations, law or policy; and on the ethical understanding and conduct of trials. The first selections of ImpACT trials will be presented, along with a discussion of the methodologic problems inherent in assessing impact and comparing trials across different health disciplines.