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## *Abstract*

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**PI Title:** ASSISTANT PROFESSOR OF GENERAL INTERNAL

**Project Title:** ELECTRONIC KNOWLEDGE BASED PUBLI OF RANDOMIZED TRIALS

**Abstract:** DESCRIPTION (adapted from the Abstract): Billions of dollars are spent annually on randomized clinical trials (RCTs), yet their results are often difficult to find, interpret, and apply to clinical care. Clinicians and policy makers are therefore turning increasingly to systematic reviews for comprehensive summaries and interpretations of RCT evidence. However, problems with the accuracy, completeness, and standardization of trial reports continue to hinder the work of systematic reviewers. Consequently, the application of RCT evidence to clinical care remains inefficient and ineffective. To improve this situation, we propose that journals publish RCTs not just as text articles, but also as entries into standardized knowledge bases (trial banks) that contain all the trial information necessary for methodologically rigorous reviews of RCTs. With trial-bank publishing, the complete details of the design, execution, and results of a trial will be available for computer-based reasoning immediately upon that trial's publication. Our long-term objective is to catalyze the worldwide publication of RCTs into openly accessible trial banks that are specifically designed to support the computer-assisted application of RCTs to clinical care. JAMA and the Annals of Internal Medicine (Annals) have agreed to experiment with trial-bank publishing. Specific Aim 1 is to build a tool for entering trials into trial banks using UMLS master terms and according to trial-bank reporting guidelines. Specific Aim 2 is to publish approximately 60 RCTs as both web-accessible trial-bank entries and as text reports in JAMA or the Annals. We will recruit clinicians and systematic reviewers to read the articles, view the trial-bank entries on the web, and comment on how their information needs were met. In Specific Aim 3, researchers from the UCSF-Stanford Evidence-Based Practice Center will enter the RCTs that they are reviewing into trial banks, and researchers from the VA Cooperative Studies Program will use trial banks to manage their RCT protocols. We will survey these researchers to evaluate our trial-bank design for its support of systematic reviewing and trial registration. Based on the work in Aims 1-3, we will define an open trial-bank application programming interface and test its ability to interface two RCT reasoning systems to our trial banks (Specific Aim 4). If we meet our aims, we will have shown that trial-bank publishing is feasible, and that trial banks are useful. We will also have laid the groundwork for a critical informatics infrastructure that will help us to improve the management, dissemination, and use of valuable RCT

information.

**Thesaurus Terms:**

clinical trial, information system, publication  
Internet, computer assisted medical decision making, computer program /software, journal,  
vocabulary development for information system  
human data

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