The Trial Bank System: Capturing Randomized Trials for Evidence-Based Medicine

Ida Sim, MD, PhD, Ben Olasov, MS, Simona Carini, MA
University of California, San Francisco, CA

Background

Randomized controlled trials (RCTs) are one of the best sources of evidence for the scientific practice of medicine. However, RCT findings are published only as text articles that are of limited machine understandability. The Trial Bank system captures information about the design, execution, and summary results of RCTs into a structured electronic knowledge base called RCT Bank. The RCT Bank data model is based on a task analysis of systematic reviewing, the canonical method for interpreting RCTs for clinical application.

RCTs accepted for publication in *JAMA* or the *Annals of Internal Medicine (Annals)* are now co-published in RCT Bank (1). By capturing all the information needed for rigorous interpretation of a trial's validity and conclusions, RCT Bank serves as a shared machine-understandable repository of RCTs for computer-assisted evidence-based medicine.

Bank-a-Trial

Bank-a-Trial consists of over 135 dynamically generated web pages that allow users such as clinical investigators and systematic reviewers to enter information about a trial's design, execution, and summary results into RCT Bank. Users are assumed to be familiar with clinical trial terms (e.g., primary hypothesis) but not with knowledge modeling. Information is collected in 11 broad categories based on an extension of the CONSORT trial reporting recommendations (2): 1) Trial Administration, 2) Background, 3) Design, 4) Entrance Criteria, 5) Randomization, 6) Interventions, 7) Outcomes, 8) Enrollment, 9) Followup and Compliance, 10) Results, and 11) Conclusions.

The order of data entry is slightly constrained to allow the customization of several data entry pages. Thus, users must describe study interventions and outcomes before describing subject enrollment and followup. Then, once all this information has been entered, the results entry pages become available and are customized to the study's interventions, outcomes, and subject enrollment.

For each entrance criterion, intervention, co-intervention, outcome, and subgroup, users are asked to select a single descriptive UMLS term using a built-in UMLS interface. When available, the selected term's definition is provided to ensure that the most appropriate term has been selected. Bank-a-Trial then stores the original search string, the String Unique Identifier (SUI) of the selected term, and the Concept Unique Identifier (CUI). Other Bank-a-Trial data fields are either free text or pick lists.

RCT Presenter

RCT Presenter allows public browsing of RCT Bank entries, while SecurePresenter allows authorized users to browse access-controlled entries. Users can browse the information, view short or long summaries, or request specific trial information. Several trial reporting and quality assessment guidelines (e.g., Cochrane and CONSORT) are available with direct hyperlinks to the relevant information for the selected trial, so that users can assess trial quality with ease. Users can also generate arbitrary tables of data across selected RCT Bank entries. This feature is particularly useful for exploring clinical and design heterogeneity among trials for systematic reviewing. Java- and Perl-based APIs are available for direct programmatic access to RCT Bank.

Results

We have captured into RCT Bank 19 RCTs with diverse interventions (multi-step drug regimens, procedures, and counseling), outcomes (dichotomous, continuous, categorical, and scored instruments), and results (intention-to-treat and efficacy results of univariate, multivariate, survival, and regression analyses). The average time for trial entry is 8 hours, although this time varies greatly with the complexity of the study. Both the *JAMA* and *Annals* websites have direct links to the RCT Presenter version of co-published RCTs. Outside users of our software include the Cochrane HIV/AIDS Review Group, and the ALCHEMIST decision support system (3), which uses RCT Bank as its RCT knowledge base.

Conclusion

The Trial Bank system captures essential RCT information into a structured knowledge base that is specifically designed for supporting rigorous computer-assisted evidence-based medicine.

1. *Sim I, Owens DK, Lavori PW, Rennels GD. Electronic Trial Banks: A Complementary Method for Reporting Randomized Trials. Med Decis Making 2000;20(4):440-450.*
2. *CONSORT. Available at: http://www.consort-statement.org/. Accessed February 13, 2003.*
3. *Sanders GD, Nease RF, Jr., Owens DK. Publishing web-based guidelines using interactive decision models. J Eval Clin Pract 2001;7(2):175-89.*