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# Publication of Clinical Trials in *JAMA*
## Information for Authors

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FULFILLING THE KEY OBJECTIVE OF *JAMA*, "TO PROmote the science and art of medicine and the betterment of the public health,"[1] involves publishing the most important biomedical investigations and clinical research articles possible. Rigorously conducted randomized clinical trials (RCTs) provide the highest level of scientific evidence for interventions and treatment to enable physicians and other practitioners to provide better care for patients and ultimately to improve the health of the public. Therefore, publication of high-quality, major RCTs represents a top priority for *JAMA*.

*JAMA* has published a substantial number of major RCTs, including landmark trials that were immediately practice changing[2,3]; major clinical trials with important practical application and implications[4,5]; and innovative, cutting-edge trials that have advanced biomedical research.[6,7] Although observational studies and systematic reviews also are extremely important and valuable sources of scientific and clinical information, RCTs will continue to receive the highest consideration for publication.

For authors of RCTs, *JAMA* offers the advantages of large circulation (print circulation of more than 350 000), extensive reach (approximately 2 million Web site page views per week), high impact factor (23.2), and short time to publication (median of 81 days from submission to acceptance, and 37 days from acceptance to publication). The Instructions for Authors[8] published in this issue of *JAMA* includes detailed information about manuscript preparation and submission. Many aspects of these instructions are specific for clinical trials and should be helpful for authors preparing manuscripts reporting results of RCTs. Several important features related to RCTs deserve emphasis.

First, as a condition of consideration for publication, *JAMA* requires that all RCTs must be registered in a public trials registry that is acceptable to the International Committee of Medical Journal Editors (ICMJE)[9,10] and that requires the minimum registration data set as described by the ICMJE. For *JAMA*, the acceptable trial registries include the following: Australian New Zealand Clinical Trials Registry (http://www.anzctr.org.au); ClinicalTrials.gov (http://www.clinicaltrials.gov); ISRCTN Register (http://isrctn.org); the Nederlands Trial Register (http://www.trialregister.nl/trialreg/index.asp); and UMIN Clinical Trials Registry (http://www.umin.ac.jp/ctr). Clinical trials for which patient enrollment began after July 2005 should have been registered before the onset of patient enrollment. All clinical trials, regardless of when they were completed, must have been registered and these trials, as well as secondary analyses of the original trial data, must include the trial registration number in the abstract of the manuscript at the time of submission. *JAMA*'s requirement for trial registration differs somewhat from requirements for registration in the recently enacted Food and Drug Amendments Act of 2007[11]; for instance, *JAMA* requires registration of all RCTs (except for phase 1 trials) that randomize human research participants to an intervention, not only those trials involving drugs or devices subject to provisions of the Federal Food, Drug, and Cosmetic Act.

Second, authors of clinical trials should follow the CONSORT guidelines[12] for reporting RCT results, including submitting a detailed patient flow diagram. For efficacy trials, the primary results should be presented based on intention-to-treat analysis, including and accounting for all randomized patients in the analysis, and if necessary, using appropriate methods to account for missing data (such as imputation methods, baseline values carried forward, etc). Other analyses, such as "completers" or "per-protocol" analyses, may be reported, but the intention-to-treat analysis generally should be reported as the primary analysis. In addition, authors are encouraged to submit protocols of RCTs along with their manuscripts.

Third, for all RCTs, data analysis must be conducted by an academic statistician. For industry-sponsored RCTs in which the data analysis is conducted only by statisticians employed by a company sponsoring the research, *JAMA* requires that a statistical analysis also be conducted by an independent statistician at an academic institution, such as a medical school, academic medical center, or government research institute, that has oversight over the person conducting the analysis and that is independent of the commercial sponsor.[13] The independent statistician should review the study protocol and determine the appropriateness of the prespecified data analysis plan, should receive the entire raw data set, and should conduct an independent data analysis; the results of the independent analysis should be the results reported in the manuscript.

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**Table.** *JAMA* Editors, Contact Information, and Areas of Expertise

| Editor and E-mail Address | Area(s) of Expertise |
|---|---|
| Catherine D. DeAngelis, MD, MPH cathy.deangelis@jama-archives.org | Any topic |
| Phil B. Fontanarosa, MD, MBA phil.fontanarosa@jama-archives.org | Any topic, *JAMA*-EXPRESS |
| Richard M. Glass, MD richard.glass@jama-archives.org | Psychiatry |
| Margaret A. Winker, MD margaret.winker@jama-archives.org | Geriatrics, dementia, clinical pharmacology |
| Drummond Rennie, MD drummond.rennie@ucsf.edu | Nephrology |
| Annette Flanagin, MA, RN annette.flanagin@jama-archives.org | Global health, nursing, violence and human rights |
| Robert M. Golub, MD robert.golub@jama-archives.org | General internal medicine, primary care, health services |
| Derek C. Angus, MD, MPH angusdc@upmc.edu | Critical care |
| Helene M. Cole, MD helene.cole@jama-archives.org | Women's health |
| Thomas B. Cole, MD, MPH tbcole@bellsouth.net | Injury control, public health |
| David S. Cooper, MD dcooper@lifebridgehealth.org | Endocrinology |
| David R. Flum, MD, MPH daveflum@u.washington.edu | Surgery |
| David H. Mark, MD, MPH david.mark@jama-archives.org | Technology assessment |
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| Boris Pasche, MD, PhD b-pasche@northwestern.edu | Hematology/oncology, cancer genetics |
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| Jody W. Zylke, MD jody.zylke@jama-archives.org | Pediatrics |

While this approach involves additional effort, time, and cost, the independent verification of data and analysis provides an important additional level of institutional oversight. The independent analysis not only increases the credibility of these studies, but also should help to avoid the perception of and potential for biased reporting that may result from the inherent conflict of interest present when the data management and statistical analysis are conducted only by employees of the sponsor that stands to benefit from the study results. To our knowledge, *JAMA* is the only general medical journal with this policy. Since implementation of this policy for independent statistical analysis in 2005,[13] the number of RCTs submitted to *JAMA* has continued to increase each year.

In addition, to provide a resource for authors and to facilitate submission to *JAMA*, authors of RCTs are strongly encouraged to contact *JAMA* editors for inquiries about the suitability of their trial (completed, nearing completion, or ongoing) for potential publication in *JAMA*; information about timelines for submission, review, and editorial decisions; and other questions and issues. A listing of the *JAMA* editors along with their specialty area or topic area of expertise and e-mail contact information is included in the TABLE. In addition, for major RCTs that have immediate clinical implications, authors are encouraged to request consideration for *JAMA*-EXPRESS[14] to determine whether the manuscript qualifies for expedited review and publication, and perhaps coordination of publication with presentation at a major scientific meeting. For RCTs that qualify for *JAMA*-EXPRESS, the median time from submission to publication is 42 days.

*JAMA*'s large circulation, high impact factor, prompt time to publication, and frequent media coverage provide an ideal mechanism for wide dissemination and communication of results of RCTs to physicians, other health care professionals, the medical research community, policy makers, and the public. We invite and encourage authors to consider *JAMA* as their journal of first choice for publication of important RCTs.

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