

Clinical trials: innovation, progress and controversy

Greg S Martin

Department of Pulmonary,
Allergy and Critical Care, Emory
University, Atlanta, Georgia, USA

The *Open Access Journal of Clinical Trials* began in 2009 with the goal of being an authoritative, open access source for international, peer-reviewed publications in the field of human research and clinical trials. Since then, the *Open Access Journal of Clinical Trials* has published approximately 30 high-quality articles on original research, innovative reviews, and critical commentaries. These articles have spanned many aspects of clinical trials wonderfully, including trial design and management; legal, ethical and regulatory issues of clinical trials; subject participation and retention in clinical trials; and data collection and data management. The breadth of subjects covered is remarkable, with articles discussing study subject enrollment, engagement, and retention;¹⁻⁴ the effects of participant heterogeneity on intermediate phase clinical trials;⁵ important methodological concerns with complementary and alternative medications;⁶ modern issues with clinical-trial data management;⁷ and state-of-the-art reviews of clinical importance such as pharmacological drug toxicity⁸ and biomarkers in cardiovascular diseases.⁹ To complement these contemporary commentaries and reviews, the *Open Access Journal of Clinical Trials* has published original research in a number of different fields in medicine, biostatistics, and epidemiology. Perhaps even more remarkable than the breadth of subjects is the international representation of authors, who hail from Europe, Africa, Australasia, and North America. As a testament to the diversity and value presented by the *Open Access Journal of Clinical Trials*, I encourage you to browse the recent editions and pick one of the articles that piques your interest.

Authors of manuscripts submitted to the *Open Access Journal of Clinical Trials* have enjoyed rapid review and publication, with the first set of reviewer comments currently being returned in an average of only 10 days. This is remarkable in an era of burgeoning clinical research and growth in the biomedical sciences, and authors have found that our peer reviewers' comments are both focused and critically useful for improving their manuscript. The open access format and online publication process have enabled the reviewers and editorial staff to work more efficiently despite the international nature of the submissions and the reviewers. In addition, the open access journal format and electronic nature of the journal makes published manuscripts freely available to anyone in the world. Another benefit of the manuscript system used by the *Open Access Journal of Clinical Trials* is the opportunity for authors to become "Favored Authors" to permit fast-tracking and personal coordination of submitted

Correspondence: Greg S Martin
Department of Pulmonary, Allergy and
Critical Care, Emory University, 49 Jesse
Hill Jr Drive SE, Atlanta, GA 30303, USA
Tel +1 404 616 0148
Fax +1 404 616 5008
Email greg.martin@emory.edu

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With such an outstanding start to a new journal, the future of *Open Access Journal of Clinical Trials* is bright indeed! The field of clinical and translational research, particularly that of clinical trials, continues to grow exponentially. If news reported through Google Trends regarding clinical research is any indication, the growth of both clinical research and clinical trials outpaces research news reports on any other subjects.¹⁰ Future issues of the *Open Access Journal of Clinical Trials* will spotlight areas of particular interest or innovation in the field of clinical trials. There is tremendous interest in areas of controversy, such as the review of clinical trials by multiple ethical boards (or institutional review boards) and the related impact on trial conduct and efficiency,¹¹ as well as methods to maximize benefits to trial participants in areas of uncertainty and concerns about equipoise.¹² The recent development of virtual clinical trials has the potential to revolutionize the way in which clinical trials are conducted,¹³ and proposals for collaborative trials with unified protocols and direct comparisons could equally transform the process for drug and device development and approval in countries throughout the world.¹⁴ Novel approaches in clinical trial design and adaptive randomization, purporting to improve patient safety and trial efficiency while minimizing ethical concerns about exposure to inferior treatments, are inevitable parts of future clinical trial reports. New regulations intended to streamline regulatory procedures for clinical trials while enhancing the protection of human subjects are of equally high interest.¹⁵ Perhaps most important for patients and our society, patient-centered outcomes research, as promulgated in US health care reform,¹⁶ is a new twist on outcomes research and comparative effectiveness research that will include more community engagement and knowledge translation to ensure that clinical trial discoveries really reach the people that need them.¹⁷

For those of you interested in the *Open Access Journal of Clinical Trials* and the field of clinical trials, please do not

hesitate to contact me. I am eager for any comments about the papers we publish, whether they are positive, negative, or simply provide further information.

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